REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the nine months ended September 30, 2006
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Unearned	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Compensation	Deficit	Loss	Equity	Loss
Balance, December 31, 2005	2,347	$2	54,092	$54	$700,011	$(315)	$(585,280)	$(470)	$114,002	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			523	1	4,882				4,883	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(50)		50							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					13,508				13,508	
Adjustment to reduce unearned compensation upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss							(71,366)		(71,366)	$(71,366)
Change in net unrealized loss on marketable securities								375	375	375
Balance, September 30, 2006	2,297	$2	54,784	$55	$719,157	—	$(656,646)	$(95)	$62,473	$(70,991)

The accompanying notes are an integral part of the financial statements.

Celltrion Exhibit - 1017 (Part 4) Pg. 3912
Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30, 2006	2005
Cash flows from operating activities		
Net loss	$ (71,366)	$ (65,774)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	11,196	11,624
Non-cash compensation expense	13,542	17,624
Cumulative effect of a change in accounting principle	(813)	
Changes in assets and liabilities		
Decrease in accounts receivable	28,581	32,566
Decrease (increase) in prepaid expenses and other assets	364	(956)
Decrease in inventory	3,524	1,208
Decrease in deferred revenue	(12,503)	(9,398)
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(2,753)	2,657
Total adjustments	41,138	55,325
Net cash used in operating activities	(30,228)	(10,449)
Cash flows from investing activities		
Purchases of marketable securities	(252,037)	(91,078)
Sales or maturities of marketable securities	261,749	185,882
Capital expenditures	(1,603)	(4,613)
Net cash provided by investing activities	8,109	90,191
Cash flows from financing activities		
Net proceeds from the issuance of stock	4,883	1,122
Other	390	
Net cash provided by financing activities	5,273	1,122
Net (decrease) increase in cash and cash equivalents	(16,846)	80,864
Cash and cash equivalents at beginning of period	184,508	95,229
Cash and cash equivalents at end of period	$ 167,662	$ 176,093

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three and nine months ended September 30, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2006	2005
Net loss (Numerator)	$(27,410)	$(34,652)
Weighted-average shares, in thousands (Denominator)	57,011	55,978
Basic and diluted net loss per share	$ (0.48)	$ (0.62)

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Nine Months Ended September 30,	
	2006	2005
Net loss (Numerator)	$(71,366)	$(65,774)
Weighted-average shares, in thousands (Denominator)	56,884	55,903
Basic and diluted net loss per share	$ (1.25)	$ (1.18)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the September 30, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,082	13,236
Weighted average exercise price	$ 14.35	$ 14.54
Restricted Stock:		
Weighted average number, in thousands	—	149
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

	Nine months ended September 30,	
	2006	2005
Stock Options:		
Weighted average number, in thousands	14,220	13,335
Weighted average exercise price	$ 14.31	$ 14.61
Restricted Stock:		
Weighted average number, in thousands	31	188
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by $813 and is included in the Company's operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on the Company's loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to the Company's cash flows for these respective periods.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals,

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. The 1990 Incentive Plan has expired and there will be no future awards from the 1990 Incentive Plan. The Company has issued Incentive Stock Options ("ISOs") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of September 30, 2006, there were 6,563,402 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At September 30, 2006, there were 13,967,474 stock options outstanding with exercise prices ranging from $4.83 to $51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents in January 2005 vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the nine months ended September 30, 2006 is presented in the following table:

	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Intrinsic Value (in thousands)
Stock options outstanding at January 1, 2006	14,719,492		$14.23	
Stock options granted	280,900		$14.90	
Stock options exercised	(552,785)		$ 9.72	
Stock options forfeited	(315,115)		$10.47	
Stock options expired	(165,018)		$24.17	
Stock options outstanding at September 30, 2006	13,967,474	6.30	$14.39	$59,450
Stock options vested and exercisable	7,087,863	4.89	$17.79	$24,221

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

The total intrinsic value of stock options exercised during the first nine months of 2006 and 2005 was $3,548 and $220, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") recognized in operating expenses totaled $4,762 and $5,439, respectively, which included $94 and $65, respectively, of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled $13,243, which included $34 previously capitalized in inventory, and $16,166, respectively. In addition, for the nine months ended September 30, 2005, $147 of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was $19,132 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon the Company's products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three and nine months ended September 30, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended September 30, 2006 and 2005 was $8.30 and $5.12 per option, respectively. The weighted-average fair value of the options granted during the nine months ended September 30, 2006 and 2005 was $9.75 and $5.79 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended September 30,	
	2006	2005
Expected volatility	65%	70%
Expected lives from grant date	5.5 years	5.0 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.74%	4.00%

	Nine months ended September 30,	
	2006	2005
Expected volatility	67%	75%
Expected lives from grant date	6.5 years	6.2 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.76%	3.96%

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the nine months ended September 30, 2006 is presented in the following table:

	Number Of Shares	Weighted Average Grant Date Fair Value
Restricted stock outstanding as of January 1, 2006	95,188	$11.16
Restricted stock released	(93,485)	$11.18
Restricted stock forfeited	(1,703)	$ 9.74
Restricted stock outstanding as of September 30, 2006	—	

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the nine months ended September 30, 2006. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation was combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

For the three months ended September 30 2005, the Company recognized compensation expense related to Restricted Stock awards of $482. For the nine months ended September 30, 2006 and 2005, the Company recognized compensation expense

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

related to Restricted Stock awards of $299 and $1,458, respectively. As of September 30, 2006, there were no unvested shares of restricted stock outstanding and all compensation expense related to these awards had been recognized.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2006 and December 31, 2005 are $439 and $234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2005 and December 31, 2004 are $252 and $550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are $1,884 and $632, respectively, of accrued Company 401 (k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2006 and December 31, 2005 are $354 and $1,228, respectively, of accrued interest income. Included in marketable securities at September 30, 2005 and December 31, 2004 are $1,110 and $2,607, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as the Company completes activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

2006 workforce reductions will approximate $2.6 million, including $0.2 million of non-cash expenses in 2005.

Severance costs associated with the workforce reduction plan that were charged to expense, or credited to adjust original cost estimates, during the three and nine months ended September 30, 2006 consist of the following:

		Three months ended September 30, 2006		
	Accrued liability at June 30, 2006	Costs charged (credited) to expense	Costs paid or settled in 2006	Accrued liability at September 30, 2006
Employee severance, payroll taxes, and benefits	$ 463	$ (44)	$ (273)	$ 146
Other severance costs	1	6	(7)	—
Total	$ 464	$ (38)	$ (280)	$ 146

		Nine months ended September 30, 2006		
	Accrued liability at December 31, 2005	Costs charged to expense	Costs paid or settled in 2006	Accrued liability at September 30, 2006
Employee severance, payroll taxes, and benefits	$ 907	$ 312	$ (1,073)	$ 146
Other severance costs	176	26	(202)	—
Total	$ 1,083	$ 338	$ (1,275)	$ 146

These severance costs are included in the Company's Statement of Operations for the three and nine months ended September 30, 2006 as follows:

Three months ended September 30, 2006	Research & development
Employee severance, payroll taxes, and benefits	$ (44)
Other severance costs	6
Total	$ (38)

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Nine months ended September 30, 2006	Research & development	General & administrative
Employee severance, payroll taxes, and benefits	$ 314	$ (2)
Other severance costs	26	—
Total	$ 340	$ (2)

For segment reporting purposes (see Note 11), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of September 30, 2006 and December 31, 2005 consist of the following:

	September 30, 2006	December 31, 2005
Receivable from the sanofi-aventis Group	$ 7,326	$ 36,412
Receivable from Merck & Co., Inc.	511	27
Other	103	82
	$ 7,940	$ 36,521

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The Company held no inventories at September 30, 2006. Inventories as of December 31, 2005 consist of the following:

	December 31, 2005
Raw materials	$ 278
Work-in-process	1,423
Finished products	1,203
	$ 2,904

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2006 and December 31, 2005 consist of the following:

	September 30, 2006	December 31, 2005
Accounts payable	$ 3,657	$ 4,203
Accrued payroll and related costs	5,952	10,713
Accrued clinical trial expense	2,145	3,081
Accrued expenses, other	2,258	3,048
Interest payable on convertible notes	5,042	2,292
	$ 19,054	$ 23,337

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and nine months ended September 30, 2006 and 2005, the components of comprehensive loss are:

	Three months ended September 30,	
	2006	2005
Net loss	$ (27,410)	$ (34,652)
Change in net unrealized gain (loss) on marketable securities	378	27
Total comprehensive loss	$ (27,032)	$ (34,625)

	Nine months ended September 30,	
	2006	2005
Net loss	$ (71,366)	$ (65,774)
Change in net unrealized gain (loss) on marketable securities	375	87
Total comprehensive loss	$ (70,991)	$ (65,687)

10. National Institutes of Health Grant

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. The NIH grant provides a minimum of $17.9 million in funding over a five-year period, subject to compliance with

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

its terms and annual funding approvals, for the Company's use of its VelociGene® technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells ("ES Cells") which can be used to produce knockout mice. The Company will also receive another $1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In September 2006, we recognized contract research and development revenue of $57 from the NIH Grant.

11. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produced an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The table below presents information about reported segments for the three and nine months ended September 30, 2006 and 2005.

	Three months ended September 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 11,448	$4,176	—	$ 15,624
Depreciation and amortization	3,447	— (1)	$ 261	3,708
Non-cash compensation expense	4,632	130	—	4,762
Interest expense	—	—	3,011	3,011
Net (loss) income	(29,379)	1,122	847 (2)	(27,410)
Capital expenditures	441	—	—	441

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended September 30, 2005			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 11,533	$4,661	—	$ 16,194
Depreciation and amortization	3,674	— (1)	$ 261	3,935
Non-cash compensation expense	5,703	218	—	5,921
Interest expense	—	—	3,011	3,011
Net (loss) income	(35,802)	1,415	(265) (2)	(34,652)
Capital expenditures	575	—	—	575

	Nine months ended September 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 41,026	$12,075	—	$ 53,101
Depreciation and amortization	10,413	— (1)	$ 783	11,196
Non-cash compensation expense	13,220	322	(813) (3)	12,729
Interest expense	—	—	9,033	9,033
Net (loss) income	(78,528)	4,359	2,803 (2)	(71,366)
Capital expenditures	1,409	—	—	1,409
Total assets	57,530	1,445	296,211 (4)	355,186

	Nine months ended September 30, 2005			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 38,580	$10,189	—	$ 48,769
Depreciation and amortization	10,841	— (1)	$ 783	11,624
Non-cash compensation expense	17,316	308	—	17,624
Other contract income	30,640	—	—	30,640
Interest expense	—	—	9,035	9,035
Net (loss) income	(67,031)	2,777	(1,520) (2)	(65,774)
Capital expenditures	4,327	—	—	4,327
Total assets	72,037	5,380	341,858 (4)	419,275

(1) Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

(2) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the nine months ended September 30, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 3).

(3) Represents the cumulative effect of adopting SFAS 123R (see Note 3).

(4) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

12. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

13. Future Impact of Recently Issued Accounting Standards

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No, 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Management is currently evaluating the potential impact of adopting FIN 48 on the Company's financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. The Company will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 157 on the Company's financial statements.

14. Subsequent Event — New Research and Development Agreement

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC ("Bayer") to globally develop, and commercialize outside the United States, the Company's Vascular Endothelial Growth Factor ("VEGF") Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of $75.0 million. In addition, the Company is eligible to receive up to $110.0 million in

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

development and regulatory milestones, including a total of $40.0 million upon the initiation of Phase 3 trials in defined major indications. The Company is also eligible to receive up to an additional $135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200.0 million.

The Company will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, the Company is responsible for any future commercialization of the VEGF Trap-Eye and has retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

2007: Up to $50.0 million shared equally; we are solely responsible for up to the next $40.0 million; over $90.0 million shared equally.

2008: Up to $70.0 million shared equally, we are solely responsible for up to the next $30.0 million; over $100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to the VEGF Trap-Eye.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and the IL-1 Trap (rilonacept) in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. In October 2006, we entered into a collaboration with Bayer HealthCare LLC for the development of the VEGF Trap-Eye. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the strength of the VelocImmune platform, which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move two new antibody candidates into clinical trials each year going forward beginning in 2007. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of September 30, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis. Currently, the collaboration is conducting three Phase 2 studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of SMA. In addition, four new Phase 2 single-agent studies are beginning in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas. We and sanofi-aventis are working to finalize plans with NCI/CTEP for at least six additional trials in different cancer types.

Sanofi-aventis and Regeneron intend to conduct three Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, the first of which is planned to begin in early 2007. Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are in progress in a variety of cancer types to support the planned Phase 3 clinical program. The companies have previously summarized information from two of these safety and tolerability trials. One study is evaluating the VEGF Trap in combination with oxaliplatin, 5-flourouracil, and leucovorin (FOLFOX4) in a Phase 1 trial of patients with advanced solid tumors. Another study is evaluating the VEGF Trap in combination with irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a Phase 1 trial of patients with advanced solid tumors. Abstracts published in the 2006 ASCO Annual Meeting Proceedings reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular

system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to $400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States, of the VEGF Trap-Eye. Under the agreement we and Bayer will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic

eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare and can earn up to $110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135.0 million in sales milestones if total annual sales of the VEGF Trap outside the United States achieve certain specified levels starting at $200 million. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Detailed information about this agreement is included in the section below entitled "Collaboration with Bayer HealthCare."

In the second quarter of 2006, we initiated a 150 patient, 12 week, Phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. Regeneron is initiating a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in AMD. A Phase 3 trial of the VEGF Trap-Eye in wet AMD utilizing the new formulation is planned to begin in early 2007.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with DME.

At the 2006 American Society of Retinal Specialists (ASRS) annual meeting in France, we updated the positive preliminary results from a Phase 1 trial of the VEGF Trap-Eye in patients with wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye). Patients were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. In wet AMD, the leakiness of the abnormal blood vessels in the eye can lead to increased retinal thickness. On average, patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness. Excess retinal thickness, as determined by ocular coherence tomography (OCT), is a clinical measure of disease activity in wet AMD. As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness resulting from the disease process was 194 microns at baseline. Following a single intravitreal dose of the VEGF Trap-Eye, median excess retinal thickness was reduced to 60 microns, an improvement that was sustained over a six week period. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline, which was reduced to 27 microns at six weeks after the single dose of the VEGF Trap-Eye.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as ≤15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at six weeks. In the two highest dose groups (2 mg and 4 mg), the mean

improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis™ (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap (rilonacept) — Inflammatory Diseases

The IL-1 Trap (rilonacept) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called *CIAS1*-related Autoinflammatory Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In October 2006, we announced positive data from a Phase 3 clinical program designed to provide two separate demonstrations of efficacy for the IL-1 Trap within a single group of adult patients suffering from CAPS. The Phase 3 program of the IL-1 Trap included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: $p < 0.0001$ and Part B: $p < 0.001$). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

We plan to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2007, following completion of a 24-week open-label extension phase. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive the IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ($p<0.0001$). Following a 9-week interval during which all patients received the IL-1 Trap, a "randomized withdrawal" study (Part B) was performed, in which the same patients were re-randomized to either switch to placebo or continue treatment with the IL-1 Trap in a double-

blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on the IL-1 Trap who had no significant change ($p<0.001$). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on the IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. The 24-week open-label extension phase is ongoing.

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin ("icy-fire"). Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of the IL-1 Trap in other indications. In particular, based on preclinical evidence that IL-1 appears to play a critical role in gout, we are preparing to initiate an exploratory study in gout in early 2007. In an ongoing pilot study in systemic juvenile idiopathic arthritis (SJIA), we observed evidence of biological activity and clinical response, but also noted clinical variability across the SJIA patients. While we continue to evaluate the IL-1 Trap in these patients, no new studies are currently planned.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In

addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2006, we had a cumulative loss of $656.6 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2006 and plans over the next 12 months are as follows:

Product Candidate	2006 Events to Date	2006-7 Plans
VEGF Trap — Oncology	• Initiated Phase 2 studies of the VEGF Trap as a single agent in AOC and NSCLA patients, and in AOC patients with SMA. • Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens • Reported encouraging preliminary results of the safety and tolerability of intravenous VEGF Trap plus FOLFOX4 and of intravenous VEGF Trap plus LV5FU2-CPT11 in separate Phase 1 trials of patients with advanced solid tumors • NCI/CTEP finalized protocols for Phase 2 trials of the VEGF Trap in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas	• Initiate up to three efficacy/safety studies of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications • Sponsor with the NCI/CTEP at least six additional exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types

Product Candidate	2006 Events to Date	2006-7 Plans
VEGF Trap-Eye	• Reported positive preliminary results from Phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg • Initiated Phase 2 trial in wet AMD utilizing intravitreal injections • Initiated safety and tolerability study of the new formulation of the VEGF Trap-Eye in patients with AMD • Initiated Phase 1 trial in DME • Initiated collaboration with Bayer HealthCare	• Report preliminary results of Phase 2 trial in wet AMD utilizing intravitreal injections • Initiate Phase 3 trial in wet AMD utilizing intravitreal injections of the VEGF Trap-Eye • Explore additional eye disease indications
IL-1 Trap (rilonacept)	• Reported positive results from efficacy portion of Phase 3 trial of the IL-1 Trap in CAPS • Reported positive preliminary results from ongoing Phase 1 trial in SJIA	• File Biologics License Application with the FDA for CAPS • Evaluate the IL-1 Trap in other disease indications in which IL-1 may play an important role

Collaboration with Bayer Healthcare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the VEGF Trap-Eye. Under the terms of the agreement, Bayer made a non-refundable up-front payment to us of $75.0 million. In addition, we are eligible to receive up to $110.0 million in development and regulatory milestones, including a total of $40.0 million upon the initiation of Phase 3 trials in defined major indications such as wet AMD and DME. We are also eligible to receive up to an additional $135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200.0 million.

We will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, we are responsible for any future commercialization of the VEGF Trap-Eye and have retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

2007: Up to $50.0 million shared equally; we are solely responsible for up to the next $40.0 million; over $90.0 million shared equally.

2008: Up to $70.0 million shared equally, we are solely responsible for up to the next $30.0 million; over $100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We will use our VelociGene® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We have also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our VelociGene technology in the Knockout Mouse Project. We will generate a collection of targeting vectors and targeted mouse embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we will be entitled to receive a minimum of $17.9 million over a five-year period. We will receive another $1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We will have the right to use, for any purpose, all materials generated by us and the research consortium.

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, *Accounting for Stock-Based Compensation*, using the modified prospective method as described in SFAS 148, *Accounting for Stock-Based Compensation- Transition and Disclosure*. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions

in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by $0.8 million and is included in our operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to our cash flows for these respective periods.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") recognized in operating expenses totaled $4.8 million and $5.4 million, respectively, which, in both periods, included $0.1 million in each period of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled $13.2 million and $16.2 million, respectively. In addition, for the nine months ended September 30, 2005, $0.1 million of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was $19.1 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals $2.7 million and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average

values of the assumptions we used in computing the fair value of option grants during the three and nine months ended September 30, 2006 and 2005:

	Three months ended September 30,	
	2006	2005
Expected volatility	65%	70%
Expected lives from grant date	5.5 years	5.0 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.74%	4.00%

	Nine months ended September 30,	
	2006	2005
Expected volatility	67%	75%
Expected lives from grant date	6.5 years	6.2 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.76%	3.96%

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended September 30, 2006 and 2005

Net Loss:

We reported a net loss of $27.4 million, or $0.48 per share (basic and diluted), for the third quarter of 2006 compared to a net loss of $34.7 million, or $0.62 per share (basic and diluted), for the third quarter of 2005.

Revenues:

Revenues for the three months ended September 30, 2006 and 2005 consist of the following:

(In millions)	2006	2005	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 10.0	$ 11.2	$ (1.2)
Other	1.4	0.3	1.1
Total contract research & development revenue	11.4	11.5	(0.1)
Contract manufacturing revenue	4.2	4.7	(0.5)
Total revenue	$ 15.6	$ 16.2	$ (0.6)

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and

2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Three months ended September 30, 2006	2005
Regeneron expense reimbursement	$ 7.0	$ 8.9
Recognition of deferred revenue related to up-front payments	3.0	2.3
Total	$ 10.0	$ 11.2

Sanofi-aventis' reimbursement of our VEGF Trap expenses decreased in the third quarter of 2006 from the same period in 2005, primarily due to lower costs in the third quarter of 2006 related to our manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments increased in the third quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of September 30, 2006, $72.2 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract manufacturing revenue relates to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue decreased in the third quarter of 2006 from the same period of 2005 as we shipped less product to Merck in 2006. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the third quarter of 2006 and 2005 were $0.4 million and $0.5 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. Merck deferred revenue has been recognized as product is shipped, based upon Merck's order quantities during the term of the agreement. In September 2006, we made the final shipment of product to Merck under the Merck agreement and the remaining deferred revenue associated with the capital improvement reimbursements was recognized. Subsequent to the October 2006 expiration of the Merck agreement, we do not expect to receive any further contract manufacturing revenue from Merck.

Expenses:

Total operating expenses decreased to $43.9 million in the third quarter of 2006 from $50.6 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 574 in the third quarter of 2006 from 728 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

Operating expenses in the third quarter of 2006 and 2005 include a total of $4.7 million and $5.5 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the three months ended September 30, 2006		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 32.1	$ 2.7	$ 34.8
Contract manufacturing	3.0	0.1	3.1
General and administrative	4.1	1.9	6.0
Total operating expenses	$ 39.2	$ 4.7	$ 43.9

(In millions)	For the three months ended September 30, 2005		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 37.8	$ 3.3	$ 41.1
Contract manufacturing	3.0	0.3	3.3
General and administrative	4.3	1.9	6.2
Total operating expenses	$ 45.1	$ 5.5	$ 50.6

Research and Development Expenses:

Research and development expenses decreased to $34.8 million in the third quarter of 2006 from $41.1 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2006 and 2005:

(In millions)	Three months ended September 30,		
Research and development expenses	2006	2005(1)	Increase (Decrease)
Payroll and benefits (2)	$ 11.0	$ 12.8	($1.8)
Clinical trial expenses	3.1	7.5	(4.4)
Clinical manufacturing costs (3)	10.0	10.8	(0.8)
Research and preclinical development costs	5.5	4.5	1.0
Occupancy and other operating costs	5.2	5.5	(0.3)
Total research and development	$ 34.8	$ 41.1	($6.3)

(1) For the major categories of research and development expenses, amounts for the three months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the three months ended September 30, 2005 are unchanged from amounts previously reported.

(2) Includes $2.3 million and $2.8 million of Stock Option Expense for the three months ended September 30, 2006 and 2005, respectively.

(3) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.5 million of Stock Option Expense for both the three months ended September 30, 2006 and 2005.

Payroll and benefits decreased principally due to our lower headcount in the third quarter of 2006, as described above. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006, as we discontinued clinical development of the IL-1 Trap in adult rheumatoid

arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased as we were not actively manufacturing clinical supplies of our drug candidates during the third quarter of 2006. Research and preclinical development costs increased primarily due to higher third-party pre-clinical testing costs in connection with our VEGF Trap and VEGF Trap-Eye programs. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to $3.1 million in the third quarter of 2006 from $3.3 million in the comparable quarter of 2005 primarily because we shipped less product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to $6.0 million in the third quarter of 2006 from $6.2 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and legal expenses related to general corporate matters.

Other Income and Expense:

Investment income increased to $3.9 million in the third quarter of 2006 from $2.7 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was $3.0 million in the third quarter of 2006 and 2005. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Nine Months Ended September 30, 2006 and 2005

Net Loss:

We reported a net loss of $71.4 million, or $1.25 per share (basic and diluted), for the first nine months of 2006 compared to a net loss of $65.8 million, or $1.18 per share (basic and diluted), for the same period of 2005. Results for the first nine months of 2005 included a $25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap-Eye.

Revenues:

Revenues for the nine months ended September 30, 2006 and 2005 consist of the following:

(In millions)	2006	2005	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 38.7	$ 30.4	$ 8.3
The Procter & Gamble Company	—	6.0	(6.0)
Other	2.3	2.2	0.1
Total contract research & development revenue	41.0	38.6	2.4
Contract manufacturing revenue	12.1	10.2	1.9
Total revenue	$ 53.1	$ 48.8	$ 4.3

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104.

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Nine months ended September 30, 2006	2005
Regeneron expense reimbursement	$ 29.6	$ 23.4
Recognition of deferred revenue related to up-front payments	9.1	7.0
Total	$ 38.7	$ 30.4

Sanofi-aventis' reimbursement of our VEGF Trap expenses increased in the first nine months of 2006 from the same period in 2005, primarily due to higher costs related to our manufacture of VEGF Trap clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first nine months of 2006 from the same period in 2005, due to our January 2006 receipt of a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

Contract research and development revenue earned from Procter & Gamble decreased in the first nine months of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue increased in the first nine months of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Included in contract manufacturing revenue in the first nine months of 2006 and 2005 were $1.2 million and $1.1 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production.

Expenses:

Total operating expenses decreased to $127.3 million in the first nine months of 2006 from $143.7 million in the same period of 2005, due, in part, to our lower headcount, as previously described above. (Also see "Severance Costs" below.)

Operating expenses in the first nine months of 2006 and 2005 include a total of $13.2 million and $16.2 million of Stock Option Expense, respectively, as detailed below:

(In millions)	**For the nine months ended September 30, 2006**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 94.0	$ 7.3	$ 101.3
Contract manufacturing	7.4	0.3	7.7
General and administrative	12.7	5.6	18.3
Total operating expenses	$ 114.1	$ 13.2	$ 127.3

(In millions)	**For the nine months ended September 30, 2005**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 107.6	$ 10.1	$ 117.7
Contract manufacturing	7.1	0.3	7.4
General and administrative	12.8	5.8	18.6
Total operating expenses	$ 127.5	$ 16.2	$ 143.7

Research and Development Expenses:

Research and development expenses decreased to $101.3 million in the first nine months of 2006 from $117.7 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2006 and 2005:

(In millions)	Nine months ended September 30,		
Research and development expenses	**2006**	**2005(1)**	**Increase (Decrease)**
Payroll and benefits (2)	$ 32.7	$ 38.4	$ (5.7)
Clinical trial expenses	11.0	16.1	(5.1)
Clinical manufacturing costs (3)	28.3	32.1	(3.8)
Research and preclinical development costs	13.3	14.5	(1.2)
Occupancy and other operating costs	16.0	16.6	(0.6)
Total research and development	$ 101.3	$ 117.7	$ (16.4)

(1) For the major categories of research and development expenses, amounts for the nine months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the nine months ended September 30, 2005 are unchanged from amounts previously reported.

(2) Includes $6.1 million and $8.4 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.

(3) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.2 million and $1.6 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first nine months of 2006. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006 as we discontinued clinical development of the IL-1 Trap in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing IL-1 Trap clinical supplies, which were partially offset by higher costs related to manufacturing VEGF Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to $7.7 million in the first nine months of 2006 from $7.4 million in the comparable period of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to $18.3 million in the first nine months of 2006 from $18.6 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and administrative personnel-related costs.

Other Income and Expense:

As described above, in January 2005 we received a one-time $25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first nine months of 2005.

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time $5.6 million payment to us, which we recognized as other contract income in the first nine months of 2005.

Investment income increased to $11.0 million in the first nine months of 2006 from $7.5 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was $9.0 million in the first nine months of 2006 and 2005. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis and Merck, and investment income.

Nine Months Ended September 30, 2006 and 2005

Cash Used in Operations:

At September 30, 2006, we had $289.6 million in cash, cash equivalents, and marketable securities compared with $316.7 million at December 31, 2005. In January 2006, we received a $25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first nine months of 2006, our net loss was $71.4 million; however, cash used in our operations was only $30.2 million, principally because (i) the above-described $25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006, and (ii) we recognized non-cash compensation expense of $13.5 million and depreciation and amortization of $11.2 million for the first nine months of 2006. In the first nine months of 2005, our net loss was $65.8 million; however, cash used in our operations was only $10.4 million, principally due to (i) receipts during this period from the sanofi-aventis Group for reimbursement of VEGF Trap development expenses incurred by us and a $25.0 million clinical milestone payment earned in December 2004 and (ii) recognition of non-cash compensation expense of $17.6 million and depreciation and amortization of $11.6 million for the first nine months of 2005.

Cash (Used in) Provided by Investing Activities:

Net cash provided by investing activities was $8.1 million in the first nine months of 2006 compared to $90.2 million in the same period of 2005, due primarily to a decrease in sales or maturities of marketable securities net of purchases. In the first nine months of 2006, sales or maturities of marketable securities exceeded purchases by $9.7 million, whereas in the same period of 2005, sales or maturities of marketable securities exceeded purchases by $94.8 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to $5.3 million in the first nine months of 2006 from $1.1 million in the same period in 2005 due primarily to an increase in payments in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

The Bayer Healthcare Agreement:

Under our collaboration agreement with Bayer, Bayer made a non-refundable, up-front payment of $75.0 million to us in October 2006. Agreed upon development expenses incurred by both companies during the term of the collaboration will be shared as follows:

2007: Up to $50.0 million shared equally; we are solely responsible for up to the next $40.0 million; over $90.0 million shared equally.

2008: Up to $70.0 million shared equally, we are solely responsible for up to the next $30.0 million; over $100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as we complete activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included $0.2 million of non-cash expenses. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and 2006 workforce reductions will approximate $2.6 million, of which $2.2 million was charged to expense in the fourth quarter of 2005 and $0.4 million was charged to expense in the first nine months of 2006.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $1.8 million and $4.3 million for the first nine months of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately $2 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer. We have entered into discussions regarding a new long-term operating lease for our laboratory and office facilities in Tarrytown, New York, as the operating lease for our current Tarrytown facilities expires in December of 2007 and 2009. We expect to continue to

incur significant lease costs in future years. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the $200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of September 30, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to $200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the nine months ended September 30, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Future Impact of Recently Issued Accounting Standards

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No, 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Our management is currently evaluating the potential impact of adopting FIN 48 on our financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. We will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 157 on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately $0.5 million and $0.8 million change in the fair market value of our investment portfolio at September 30, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at September 30, 2006, compared to September 30, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of September 2006 versus the end of September 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2006, we had a cumulative loss of $656.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Until October 31, 2006, we received contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck expired in October 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the $200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the phase 3 clinical program for the IL-1 Trap in CAPS (CIAS1-related Autoinflammatory Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of the IL-1 Trap.

The efficacy and safety data from the phase 3 clinical program for the IL-1 Trap in CAPS may be inadequate to support approval for its commercialization in this indication. Moreover, if the safety data from the ongoing clinical trials testing the IL-1 Trap are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for the IL-1 Trap or we may be forced to delay the filing. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance. Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for the IL-1 Trap, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize the IL-1 Trap profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the IL-1 Trap in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses,

injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel® (Amgen) and Remicade® (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created

at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have

blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an

unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We will rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration

agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce API for our own clinical and preclinical candidates. Under a long-term manufacturing agreement with Merck, which expired in October 2006, we also produced an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. Since we no longer use our facilities to manufacture the Merck intermediate, and if clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings.

This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor (Macugen®) for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis™) for the treatment of wet AMD and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The National Eye Institue has recently received funding for a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. The marketing approval of Macugen and Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis or Macugen, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS*1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We intend to file an application with the FDA seeking approval to market the IL-1 Trap for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize the IL-1 Trap. Physicians may not prescribe the IL-1 Trap and CAPS patients may not be able to afford the IL-1 Trap if third party payers do not agree to reimburse the cost of IL-1 Trap therapy and this would adversely affect our ability to commercialize the IL-1 Trap profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including the IL-1 Trap, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Therapeutics and Clinical Program Development, Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations, and Peter Powchik, M.D., our Senior Vice President, Clinical Development. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of September 30, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 46.6% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. As of September 30, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2006, holders of Class A Stock held 29.5% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of September 30, 2006:

- our current officers and directors beneficially owned 14.4% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2006, and 33.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2006; and
- our seven largest shareholders beneficially owned 46.6% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. In addition, these seven shareholders held 53.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of September 30, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote

for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;

- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

In addition, we have a Change in Control Severance Plan and many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

Item 6. Exhibits

(a) Exhibits

Exhibit Number		Description
10.1	—	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
12.1	—	Statement re: computation of ratio of earnings to combined fixed charges.
31.1	—	Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	—	Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	—	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: November 6, 2006

By: /s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Exhibit 10.1

LICENSE AND COLLABORATION AGREEMENT

By and Between

BAYER HEALTHCARE LLC

and

REGENERON PHARMACEUTICALS, INC.

Dated as of October 18, 2006

TABLE OF CONTENTS

ARTICLE I DEFINITIONS	1
1.1 "Affiliate"	1
1.2 "Agreement"	2
1.3 "Anticipated First Commercial Sale"	2
1.4 "Approval"	2
1.5 "Aventis"	2
1.6 "Aventis Agreement"	2
1.7 "Business Day"	2
1.8 "Change of Control"	2
1.9 "Class A Stock"	3
1.10 "Clinical Supply Cost"	3
1.11 "Clinical Supply Requirements"	3
1.12 "COGS"	3
1.13 "Commercialize" or "Commercialization"	3
1.14 "Commercial Overhead Charge"	3
1.15 "Commercially Reasonable Efforts"	4
1.16 "Commercial Supply Cost"	4
1.17 "Commercial Supply Requirements"	4
1.18 "Committee"	4
1.19 "Common Stock"	5
1.20 "Company Excluded Territory Intellectual Property"	5
1.21 "Company Intellectual Property"	5
1.22 "Company Patent Rights"	5
1.23 "Consolidated Payment Report"	5
1.24 "Contract Year"	5
1.25 "Controlling Party"	5
1.26 "Country Commercialization Budget"	5
1.27 "Country Commercialization Plan"	6
1.28 "Country Commercialization Report"	6
1.29 "CPI"	6
1.30 "Develop" or "Development"	6
1.31 "Development Costs"	6
1.32 "Development FTE Cost"	7
1.33 "Development FTE Rate"	8
1.34 "Development Plan(s)"	8
1.35 "Effective Date"	8
1.36 "EMEA"	8
1.37 "Excluded Territory"	8
1.38 "Executive Officers"	8
1.39 "Existing Licenses"	8
1.40 "FDA"	8
1.41 "Field"	8
1.42 "Finished Product"	8
1.43 "First Commercial Sale"	8

1.44 "Formulated Bulk Product" 9
1.45 "FTE" 9
1.46 "GAAP" 9
1.47 "Global Development Budget" 9
1.48 "Global Development Plan" 9
1.49 "Good Practices" 9
1.50 "Governmental Authority" 9
1.51 "IAS/IFRS" 9
1.52 "ICH" 9
1.53 "IND" 9
1.54 "Joint Patent Rights" 10
1.55 "Know-How" 10
1.56 "Law" or "Laws" 10
1.57 "Lead Regulatory Party" 10
1.58 "Legal Dispute" 10
1.59 "Licensed Products" 10
1.60 "Major Market Country" 10
1.61 "Manufacture" or "Manufacturing" 10
1.62 "Marketing Approval" 10
1.63 "Medical Affairs Cost" 10
1.64 "Medical Affairs FTE Rate" 11
1.65 "Net Sales" 11
1.66 "New Information" 12
1.67 "New License" 13
1.68 "Other Shared Expenses" 13
1.69 "Out-of-Pocket Costs" 13
1.70 "Party Information" 13
1.71 "Patent Application" 13
1.72 "Patent Rights" 13
1.73 "Patents" 13
1.74 "Person" 13
1.75 "Phase 2 Trial" 13
1.76 "Phase 3 Trial" 13
1.77 "Plan" 14
1.78 "Pre-Launch Marketing Expenses" 14
1.79 "Pricing Approval" 14
1.80 "Product" 14
1.81 "Product Trademark" 14
1.82 "Promotional Materials" 14
1.83 "Quarter" or "Quarterly" 14
1.84 "Regeneron Excluded Territory Intellectual Property" 14
1.85 "Regeneron Intellectual Property" 15
1.86 "Regeneron Patent Rights" 15
1.87 "Regeneron Products" 15
1.88 "Region" 15
1.89 "Registration Filing" 15

1.90 "Regulatory Authority" 15
1.91 "Rest of World Country" 15
1.92 "Sales Force Cost" 15
1.93 "Sales Force FTE Rate" 15
1.94 "Shared Promotion Expenses" 16
1.95 "Shares of Then Outstanding Capital Stock" 17
1.96 "Sublicensee" 17
1.97 "Territory Commercialization Budget" 17
1.98 "Territory Commercialization Plan" 17
1.99 "Territory" 17
1.100 "Territory Development Plan" 17
1.101 "Territory Development Budget" 17
1.102 "Third Party" 18
1.103 "United States," "US" or "U.S." 18
1.104 "Valid Claim" 18
1.105 "VEGF" 18
1.106 "VEGF Trap" 18
1.107 "Additional Definitions." 18

ARTICLE II COLLABORATION 19

2.1 Scope of Collaboration 19
2.2 Compliance With Law 19
2.3 Further Assurances and Transaction Approvals 19
2.4 Compliance with Third Party Agreements 20
2.5 Plans 20
2.6 Limitation on Exercise of Rights Outside of Collaboration. 20
2.7 Excluded Territory Activities 22

ARTICLE III MANAGEMENT 22

3.1 Committees/Management. 23
3.2 Joint Steering Committee. 23
3.3 Joint Development Committee. 24
3.4 Joint Commercialization Committee. 25
3.5 Other Committees 27
3.6 Membership 27
3.7 Meetings 28
3.8 Decision-Making 28
3.9 Project Manager 28
3.10 Resolution of Governance Matters 28

ARTICLE IV LICENSE GRANTS 30

4.1 Regeneron License Grants 30
4.2 Company License Grants 30
4.3 Sublicensing 31
4.4 No Implied License 31
4.5 Retained Rights 31
4.6 Right of Negotiation for Excluded Territory 32

ARTICLE V DEVELOPMENT ACTIVITIES 32

5.1 Development of Licensed Products 32
5.2 Development Plans 32
5.3 Development Budgets 33
5.4 Development Reports 34
5.5 Review of Clinical Trial Protocols 34

ARTICLE VI COMMERCIALIZATION 34

6.1 Commercialization of Products in the Field in the Territory 34
6.2 Territory Commercialization Plan 34
6.3 Country Commercialization Plans 35
6.4 Commercialization Activities; Sharing of Commercial Information. 36
6.5 Product Pricing and Pricing Approvals in the Territory 37
6.6 Sales and Product Distribution in the Territory; Other Responsibilities 37
6.7 Commercialization Efforts 37
6.8 Contract Sales Force 38
6.9 Promotional Materials. 38
6.10 Promotional Claims/Compliance 38
6.11 Restriction on Bundling in the Territory 38
6.12 Inventory Management 39
6.13 Medical and Consumer Inquiries 39
6.14 Market Exclusivity Extensions 39
6.15 Post Marketing Clinical Trials 39
6.16 Activities outside the Collaboration 39
6.17 Restriction on Commercialization Activities 40
6.18 Exports from the Territory to the Excluded Territory. 40

ARTICLE VII CLINICAL AND REGULATORY AFFAIRS 41

7.1 Ownership of Approvals and Registration Filings. 41
7.2 Regulatory Coordination. 41
7.3 Regulatory Coordination with Third Parties 43
7.4 Regulatory Events 44
7.5 Pharmacovigilance and Product Complaints 45
7.6 Regulatory Inspection or Audit 45
7.7 Recalls and Other Corrective Actions 46

ARTICLE VIII MANUFACTURING AND SUPPLY 46

8.1 Formulated Bulk Product Supply in the Field in the Territory 46
8.2 Finished Product Supply in the Field in the Territory 46
8.3 Supply Agreement 46
8.4 Manufacturing Plans 47
8.5 Manufacturing Shortfall 47
8.6 Manufacturing Compliance 47

ARTICLE IX PERIODIC REPORTS; PAYMENTS 48

9.1 Upfront Payment and Milestone Payments. 48

9.2 Development Costs. 48
9.3 Periodic Reports 49
9.4 Funds Flow 50
9.5 Invoices and Documentation 51
9.6 Payment Method and Currency 51
9.7 Late Payments 51
9.8 Taxes 51
9.9 Adjustments to FTE Rates 52
9.10 Resolution of Payment Disputes 52
9.11 Budget Overruns 52

ARTICLE X DISPUTE RESOLUTION 53

10.1 Resolution of Disputes 53
10.2 Governance Disputes 53
10.3 Legal Disputes 53
10.4 Expert Panel 53
10.5 No Waiver 55

ARTICLE XI TRADEMARKS AND CORPORATE LOGOS 55

11.1 Corporate Names 55
11.2 Selection of Product Trademarks 55
11.3 Ownership of Product Trademarks 55
11.4 Prosecution and Maintenance of Product Trademark(s) 56
11.5 License to the Product Trademark(s) 56
11.6 Use of Corporate Names 56

ARTICLE XII NEWLY CREATED INVENTIONS 57

12.1 Ownership of Newly Created Intellectual Property. 57
12.2 Prosecution and Maintenance of Patent Rights. 58
12.3 Interference, Opposition and Reissue. 61

ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION 61

13.1 Third Party Infringement Suits. 61
13.2 Patent Marking 62
13.3 Third Party Infringement Claims; New Licenses. 63

ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS 63

14.1 Books and Records 64
14.2 Audits and Adjustments. 64
14.3 GAAP/IAS/IFRS 65

ARTICLE XV REPRESENTATIONS AND WARRANTIES 65

15.1 Due Organization, Valid Existence and Due Authorization 65
15.2 Knowledge of Pending or Threatened Litigation 65
15.3 Additional Regeneron Representations and Warranties 65
15.4 Disclaimer of Warranties 67

15.5 Mutual Covenants 67

ARTICLE XVI CONFIDENTIALITY 68

16.1 Confidential Information. 68
16.2 Injunctive Relief 70
16.3 Publication of New Information 70
16.4 Other Publications 70

ARTICLE XVII INDEMNITY 71

17.1 Indemnity and Insurance. 71
17.2 Indemnity Procedure 73

ARTICLE XVIII FORCE MAJEURE 75

ARTICLE XIX TERM AND TERMINATION 75

19.1 Term/Expiration of Term. 75
19.2 Termination Without Cause 75
19.3 Termination For Material Breach 76
19.4 Termination for Insolvency 77
19.5 Termination for Breach of Standstill 77
19.6 [**********] 77
19.7 Effect of Termination 77
19.8 Survival of Obligations 78

ARTICLE XX MISCELLANEOUS 79

20.1 Governing Law; Submission to Jurisdiction 79
20.2 Waiver 79
20.3 Notices 79
20.4 Entire Agreement 80
20.5 Amendments 80
20.6 Headings 80
20.7 Severability 80
20.8 Registration and Filing of the Agreement 80
20.9 Assignment 80
20.10 Successors and Assigns 81
20.11 Affiliates 81
20.12 Counterparts 81
20.13 Third-Party Beneficiaries 81
20.14 Relationship of the Parties 82
20.15 Limitation of Damages 82
20.16 Standstill Agreement 82
20.17 Termination of Standstill 83
20.18 Non-Solicitation 84
20.19 No Strict Construction 84

LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT ("Agreement"), dated as of October 18, 2006 (the "Effective Date"), is by and between BAYER HEALTHCARE LLC, a Delaware limited liability company having a principal place of business at 511 Benedict Avenue, Tarrytown, New York 10591 ("Company"), and REGENERON PHARMACEUTICALS, INC., a New York corporation having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron") (with each of Company and Regeneron referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Regeneron owns and has licensed certain Patents, Know-How and other rights related to the VEGF Trap in the Territory;

WHEREAS, Company and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory; and

WHEREAS, Regeneron and Company desire to collaborate on the Development and Manufacture of Products in the Field, and the Commercialization of Products in the Field in the Territory under the terms and conditions set forth herein (the "Collaboration").

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by

law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

1.2 "Agreement" shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.3 "Anticipated First Commercial Sale" shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.

1.4 "Approval" shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.5 "Aventis" shall mean sanofi-aventis US LLC (successor in interest to Aventis Pharmaceuticals, Inc.

1.6 "Aventis Agreement" shall mean the Collaboration Agreement, dated as of September 3, 2003, by and between Aventis and Regeneron Pharmaceuticals, Inc., as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, and the Fourth Amendment, dated as of January 31, 2006, as the same may be further amended from time to time.

1.7 "Business Day" shall mean a day on which commercial banking institutions in New York, New York are open for business.

1.8 "Change of Control" shall mean, with respect to Regeneron, any of the following events: (a) any Person is or becomes the "beneficial owner" (as such term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder, except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all classes of capital stock then outstanding of Regeneron normally entitled to vote in elections of directors; (b) Regeneron consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into Regeneron, other than (i) a merger or consolidation which would result in the voting securities of Regeneron outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of Regeneron or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (ii) a

merger or consolidation effected to implement a recapitalization of Regeneron (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of Regeneron representing a majority of the combined voting power of Regeneron's then outstanding securities; or (c) Regeneron conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly-owned Affiliate of Regeneron.

1.9 "Class A Stock" shall mean the Class A Stock of Regeneron, par value $0.001 per share.

1.10 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the Development Plans, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the Development Plans, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging and labeling such Clinical Supply Requirements, comparator agent and/or placebo, as the case may be, for activities contemplated under the Development Plans and (d) any VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements.

1.11 "Clinical Supply Requirements" shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, pre-clinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.

1.12 "COGS" for a Quarter shall mean cost (calculated in accordance with GAAP or IAS/IFRS) of Manufacturing the Licensed Products sold in the Field in the Territory in the Quarter.

1.13 "Commercialize" or "Commercialization" shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, offering for sale, having sold and/or selling a Licensed Product in the Field in the Territory, including, without limitation, market research, pre-launch marketing and educational activities, sampling and Non-Approval Trials in the Territory.

1.14 "Commercial Overhead Charge" shall mean, on a country-by-country basis in the Territory, beginning in the Contract Year of First Commercial Sale in the applicable country, an amount (agreed upon by the JFC at least eighteen (18) months prior to the Anticipated First Commercial Sale in the country) to cover [**********], such amount to be determined by the JFC as of January 1 of each following Contract Year. For the avoidance of doubt, "Commercial Overhead Charge" shall not include any amounts included in Medical Affairs Cost, Sales Force Cost, Other Shared Expenses or Shared Promotion Expenses.

1.15 "Commercially Reasonable Efforts" shall mean, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be consistent with the Collaboration Purpose and substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it, which product is at a similar stage in its development or product life and is of similar market potential (taking into consideration both anticipated total sales and overall profitability). Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the Territory Profit Split nor other payments made or required to be made from one Party to the other under this Agreement shall be considered in determining market potential (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must pay the Territory Profit Split or make milestone or any other payments hereunder to the other Party). By way of example, for purposes of determining whether Company uses Commercially Reasonable Efforts to Commercialize a Licensed Product in a Major Market Country, a basis for comparison shall be the efforts used by Company to commercialize in such Major Market Country another Company product that is wholly owned by Company, is at a similar stage of commercialization to the Licensed Product and has both anticipated total sales and overall profitability to Company in such Major Market Country substantially similar to that of the Licensed Product, taking into account total sales and total profitability of the Licensed Product in such Major Market Country, but without consideration of any of the payments required to be made from one Party to the other under this Agreement.

1.16 "Commercial Supply Cost" shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of the Commercial Supply Requirements, including, without limitation, any filling, packaging and labeling costs, and any VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.17 "Commercial Supply Requirements" shall mean, with respect to each Licensed Product, quantities of Finished Product as are required by Company to fulfill its (or its Affiliate's or Sublicensee's) requirements for commercial sales, Non-Approval Trials and Product sampling with respect to such Licensed Product in the Field in the Territory.

1.18 "Committee" means any of the JSC, JDC, JCC or JFC, each as described in Article 3 (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).

1.19 "Common Stock" shall mean the common stock of Regeneron, par value $0.001 per share.

1.20 "Company Excluded Territory Intellectual Property" shall mean Company Patent Rights and Know-How that cover, claim or are used for the Development, Manufacture and/or Commercialization of Regeneron Products under the Plans, but excluding (a) any Company Patent Rights covering the composition of any Company Products, and (b) any New Information or Party Information arising from the Development, Manufacture and/or Commercialization of Company Products.

1.21 "Company Intellectual Property" shall mean the Company Patent Rights and any Know-How of Company or any of its Affiliates.

1.22 "Company Patent Rights" shall mean those Patent Rights which (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Company or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, Patent Rights covering any formulation and delivery technologies, with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Product in the Field.

1.23 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Company (based on information reported under Sections 5.4 and 9.3) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Promotion Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter under the Global Development Plan and the Territory Development Plan, (c) Other Shared Expenses incurred by each Party for such Quarter, including the allocation of global costs pursuant to Section 3.4(b)(xii), (d) Commercial Supply Costs incurred by each Party for such Quarter and (e) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.

1.24 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2007, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.

1.25 "Controlling Party" shall mean Regeneron with respect to the filing, prosecution and maintenance of a Joint Patent Right that claims or covers a Regeneron Product (or the Manufacture or use thereof), and Company in the case of all other Joint Patent Rights.

1.26 "Country Commercialization Budget" shall mean the three-year rolling budget(s) approved by the JCC for a particular Country Commercialization Plan.

1.27 "Country Commercialization Plan" shall mean, for each Major Market Country in the Territory, the three-year rolling plan for Commercializing Licensed Products in the Field in such country, including the applicable Country Commercialization Budget, developed and approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.

1.28 "Country Commercialization Report" shall mean, for each Major Market Country in the Territory, a written report summarizing the marketing, detailing, selling and promotional activities undertaken by Company (or its Affiliate) during the previous Quarter in connection with the applicable Country Commercialization Plan, including the number of details for the Licensed Product in the Field in the country, together with a detailed project-level statement of Shared Promotion Expenses (calculated in U.S. dollars and local currency) incurred by Company (or its Affiliate) during such Quarter in the country.

1.29 "CPI" for the Excluded Territory shall mean the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index). For countries and Regions in the Territory (other than Japan), "CPI" shall mean the "EU15 CPI" (or its successor equivalent index), which is published monthly and available via Bloomberg Professional, as published by Bloomberg L.P. In Japan, "CPI" shall mean such other inflation measure or rate agreed upon by the Parties.

1.30 "Develop" or "Development" shall mean (a) activities directly and specifically relating to research, pre-clinical and clinical drug development of a Licensed Product in the Field, including, without limitation, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation, submission and maintenance of Registration Filings and Approvals (including post-marketing clinical trials imposed by applicable Law or as required by a Regulatory Authority) and activities necessary to obtain a Pricing Approval, reimbursement and/or listing on health care providers' and payers' formularies, and (b) any other development activities with respect to a Licensed Product in the Field, including, without limitation, activities to support new product formulations, delivery technologies and/or new indications in the Field either before or after the First Commercial Sale.

1.31 "Development Costs" shall mean costs incurred by a Party in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the Development Plan(s) (or prior to the first Development Plan, the Initial Development Plan), including without limitation:

(a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining and maintaining Registration Filings and Approvals (including Pricing Approvals) necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;

(b) Development FTE Costs;

(c) Clinical Supply Costs;

(d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation, (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);

(e) Pre-Launch Marketing Expenses;

(f) any license fees and other payments under Existing Licenses and New Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory (which, for the avoidance of doubt, include activities in the Excluded Territory performed under the Global Development Plan); and

(g) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.

For clarity, it is the intent of the Parties that costs included in the foregoing will not be unfairly allocated to the Licensed Products in the Field (to the extent that any development cost is attributable, in part, to products or activities outside the scope of this Agreement). For the avoidance of doubt, [**********] and as defined therein shall be considered a Development Cost under the Global Development Plan under this Agreement

1.32 "Development FTE Cost" shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the

product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate.

1.33 "Development FTE Rate" for the Excluded Territory, the Territory (other than Japan) and Japan shall mean [********] in the first Contract Year, such amount to be adjusted as of January 1, 2008 and annually thereafter by the percentage increase or decrease, if any, in the applicable CPI (determined based on the location of the Development personnel) since the Effective Date or the latest adjustment date hereunder, whichever is later, through June 30 of the prior calendar year. The Development FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.34 "Development Plan(s)" shall mean the Global Development Plan and the Territory Development Plan.

1.35 "Effective Date" shall have the meaning set forth in the introductory paragraph.

1.36 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

1.37 "Excluded Territory" shall mean the United States.

1.38 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Bayer HealthCare AG, a German corporation having a principal place of business at 51368 Leverkusen, Germany.

1.39 "Existing Licenses" shall mean the agreements listed in Schedule 4.

1.40 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.41 "Field" shall mean the treatment and/or diagnosis of any ocular disease or disorder through the local administration of any product to the eye, including, without limitation, by topical, intravitreal, periorbital, implants or other means of local administration to the eye.

1.42 "Finished Product" shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.

1.43 "First Commercial Sale" shall mean, with respect to a Licensed Product in a country in the Territory (or, solely for purposes of Section 19.7(c), in the Excluded Territory), the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

1.44 "Formulated Bulk Product" shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.45 "FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [********] per year.

1.46 "GAAP" shall mean generally accepted accounting principles in the United States.

1.47 "Global Development Budget" shall mean the three-year rolling budget(s) approved by the JSC in the Global Development Plan.

1.48 "Global Development Plan" shall mean the three-year rolling plan approved by the JSC for Developing Licensed Products in the Field as part of an integrated worldwide Development program, including the related Global Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Global Development Plan activities may be undertaken entirely or partially in the Excluded Territory if approved by the JSC. For the avoidance of doubt, the Global Development Plan will not include (a) any Development activities that are conducted or sponsored by a Party which are only required for a specific Approval in the Territory (including activities under the Territory Development Plan) or the Excluded Territory, (b) Non-Approval Trials or (c) any studies conducted for Pricing Approval or formulary approval.

1.49 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" and/or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.

1.50 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.51 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.

1.52 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.53 "IND" shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Product, as

described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.

1.54 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.

1.55 "Know-How" shall mean any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) which (a) are now or hereafter during the Term owned by, licensed to or otherwise held by (i) a Party, (ii) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement or (iii) any of Regeneron's Affiliates, with the rights to license or sublicense the same, and (b) relate to a Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Product in the Field, including, without limitation, New Information.

1.56 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

1.57 "Lead Regulatory Party" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.

1.58 "Legal Dispute" shall mean any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement.

1.59 "Licensed Products" shall mean Regeneron Products and Company Products.

1.60 "Major Market Country" shall mean [********** and [*******].

1.61 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.

1.62 "Marketing Approval" shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.

1.63 "Medical Affairs Cost" shall mean, for each country in the Territory, the product of (a) the number of office-based FTEs supporting the coordination of Non-Approval Trials related to the Licensed Products in the Field as agreed upon in the

Country Commercialization Plan or Territory Commercialization Plan and (b) the applicable Medical Affairs FTE Rate.

1.64 "Medical Affairs FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Affairs FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.65 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Licensed Products in the Field in the Territory by or on behalf of Company or its Affiliates or Sublicensees to Third Parties, less the following deductions determined in accordance with Company's standard methods as generally and consistently applied by Company:

(a) normal and customary trade, cash and/or quantity discounts allowed and taken with respect to Licensed Product sales;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates and allowances;

(c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;

(d) Third Party cash rebates and chargebacks related to sales of the Licensed Product, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory payments and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;

(g) freight, insurance and other transportation charges, to the extent included in the invoice price;

(h) tariffs, duties, excise, value-added, consumption or other taxes (other than taxes based on income), to the extent included in the invoice price; and

(i) any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within categories substantially equivalent to those listed above.

Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Company or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), Net Sales of such Combination Product for the purpose of determining the Territory Profit Split pursuant to this Agreement will be calculated by multiplying actual Net Sales of such Combination Product as determined in the first paragraph of this definition of "Net Sales" by the fraction A/(A+B), where A is the invoice price of such Licensed Product if sold separately, and B is the total invoice price of the other active ingredient(s) in the combination if sold separately. If, on a country-by-country basis, such other active ingredient(s) in the Combination Product is not sold separately in such country, but the Licensed Product component of the Combination Product is sold separately in such country, Net Sales for the purpose of determining Territory Profit Split pursuant to this Agreement for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction A/C, where A is the invoice price of the Licensed Product component if sold separately, and C is the invoice price of the Combination Product. If, on a country-by-country basis, the Licensed Product component is not sold separately in that country, Net Sales for the purpose of determining the Territory Profit Split pursuant to this Agreement for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction D/(D+E), where D is the fair market value of the portion of the Combination Product that contains the Licensed Product and E is the fair market value of the portion of the Combination Product containing the other active ingredient(s) included in such Combination Product, as such fair market values are determined by mutual agreement of the Parties through the JFC.

1.66 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by (a) either Party,(b) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement, (c) any of Regeneron's Affiliates or (d) the Parties or their Affiliates jointly, during the Term pursuant to this Agreement to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.

1.67 "New License" shall mean any license approved by the JSC, other than Existing Licenses, required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.

1.68 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 3.4(b)(xii), 7.7, 12.2(e), 12.3(b), 13.1(c), 13.3(b), 13.3(d) and 17.1(c) which, except as set forth in Section 3.4(b)(xii) or elsewhere in this Agreement, shall be shared equally between the Parties.

1.69 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with the applicable Plan.

1.70 "Party Information" shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party's or its Affiliates' technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement. For the avoidance of doubt, all confidential information disclosed by Regeneron under the terms of the confidentiality agreement between the Parties dated July 6, 2006 is hereby deemed Party Information of Regeneron.

1.71 "Patent Application" shall mean any application for a Patent.

1.72 "Patent Rights" shall mean unexpired Patents and Patent Applications.

1.73 "Patents" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.

1.74 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.

1.75 "Phase 2 Trial" shall mean a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.

1.76 "Phase 3 Trial" shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one Phase 2 Trial.

1.77 "Plan" shall mean any Country Commercialization Plan, Territory Commercialization Plan, Global Development Plan, Territory Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of Licensed Products in the Field under this Agreement.

1.78 "Pre-Launch Marketing Expenses" shall mean, on a country-by-country basis in the Territory, with respect to each Licensed Product, all Commercialization expenses to support the Licensed Products in the Field incurred prior to the First Commercial Sale of such Licensed Product in the Field in the country.

1.79 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.80 "Product" shall mean [**********]. Except as expressly set forth herein, the defined term "Product" shall refer exclusively to any such molecule Manufactured, Developed and/or Commercialized in the Field.

1.81 "Product Trademark" shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.

1.82 "Promotional Materials" shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.83 "Quarter" or "Quarterly" shall refer to a calendar quarter, except that the first Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.

1.84 "Regeneron Excluded Territory Intellectual Property" shall mean Regeneron Patent Rights and Know-How that cover, claim or are used for the Development, Manufacture and/or Commercialization of Company Products under the Plans, but excluding (a) any Regeneron Patent Rights covering the composition of any Regeneron Products, including, without limitation, the VEGF Trap, and (b) any New

Information or Party Information arising from the Development, Manufacture and/or Commercialization of Regeneron Products.

1.85 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

1.86 "Regeneron Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, Patent Rights covering formulation and delivery technologies, with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Product in the Field.

1.87 "Regeneron Products" shall mean Products which are now or hereafter during the Term owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, the VEGF Trap.

1.88 "Region" shall mean [**********] and [*******].

1.89 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.

1.90 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.

1.91 "Rest of World Country" shall mean any country in the Territory other than the Major Market Countries.

1.92 "Sales Force Cost" shall mean, for a country in the Territory, the product of (a) the number of FTEs detailing the Licensed Products in the Field in the country in accordance with the approved Country Commercialization Plan and (b) the applicable Sales Force FTE Rate. Notwithstanding the foregoing, neither "Sales Force Cost" nor, for clarity, "Shared Promotion Expenses," shall include the costs related to [**********]

1.93 "Sales Force FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of

pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.94 "Shared Promotion Expenses" shall mean the sum of the following items, in each case to the extent attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country Commercialization Plan or Territory Commercialization Plan:

(a) [**********] to cover the cost of distribution, freight, insurance and warehousing, related to the sale of Licensed Products in the Field in the Territory;

(b) bad debt attributable to Licensed Products in the Field sold in the Territory;

(c) Sales Force Cost;

(d) Medical Affairs Cost;

(e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;

(f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion (i) relate to both Licensed Products and other Company products or (ii) relate to Licensed Products in the Field in both the Territory and the Excluded Territory, in each case, as agreed upon in an approved Territory Commercialization Plan or Country Commercialization Plan;

(g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost; and

(h) Commercial Overhead Charge.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will not be unfairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Promotion Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

1.95 "Shares of Then Outstanding Capital Stock" shall mean, at any time, the issued and outstanding shares of Common Stock and Class A Stock of Regeneron at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend or reclassification of Common Stock or Class A Stock distributable, on a pro rata basis, to all holders of Common Stock and Class A Stock.

1.96 "Sublicensee" shall mean a Third Party or an Affiliate to whom Company will have granted a license or sublicense under Company's rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a "Sublicensee" will include a Third Party to whom Company will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Company a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.

1.97 "Territory Commercialization Budget" shall mean the three-year rolling budget(s) included in the Territory Commercialization Plan.

1.98 "Territory Commercialization Plan" shall mean the three-year rolling plan for Commercializing the Licensed Products in the Field in the Territory approved by the JSC, including the Territory Commercialization Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. The Territory Commercialization Plan shall set forth for each Licensed Product, the information, plans and forecasts set forth in Section 6.2.

1.99 "Territory" shall mean all the countries of the world, except the Excluded Territory.

1.100 "Territory Development Plan" shall mean the three-year rolling plan approved by the JSC for Developing the Licensed Products in the Field for a specific country (or countries) in the Territory, including the related Territory Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, the Territory Development Plan will not include (a) any Development activities that are conducted as part of the Global Development Plan or (b) Non-Approval Trials, but will include any other clinical trials of the Licensed Products in the Field in the Territory, including any studies or other activities conducted for Pricing Approval.

1.101 "Territory Development Budget" shall mean the three-year rolling budget(s) approved by the JSC in the Territory Development Plan.

1.102 "Third Party" shall mean any Person other than Company or Regeneron or any Affiliate of either Party.

1.103 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.104 "Valid Claim" shall mean a claim (a) of any issued, unexpired Patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) of any Patent Application that has not been cancelled, withdrawn or abandoned or pending for more than seven (7) years.

1.105 "VEGF" shall mean vascular endothelial growth factor.

1.106 "VEGF Trap" shall mean [**********]

1.107 "Additional Definitions." Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
Aggregate Regeneron Payment Amount	9.2(a)
Alliance Manager	3.2(a)
Collaboration	Preamble
Collaboration Purpose	3.1(b)
Company Products	2.6
Development Budget(s)	5.3
Development Overrun	9.11
Expert Panel	0.4
Global Brand	3.4(b)(i)
Global Development Balance	Schedule 2
Global True-Up	Schedule 2
Governance Dispute	10.2
Initial Development Plan	5.2
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JSC	3.1(a)
Joint Invention	12.1(b)
Manufacturing Cost	Schedule 1
Manufacturing Plan	8.4
Marketing Guidelines	3.4(b)(v)
Non-Approval Trials	6.2(j)

DEFINITION	SECTION/SCHEDULE
Non-Incurred Amount	5.3
Project Manager	3.9
Regeneron Reimbursement Amount	Schedule 2
Quarterly True-Up	Schedule 2
Term	19.1(a)
Termination Notice Period	19.2
Territory Profit Split	Schedule 2
Working Group	3.1(a)

ARTICLE II
COLLABORATION

2.1 Scope of Collaboration. The Parties will cooperate in good faith under this Agreement and each Party will use Commercially Reasonable Efforts to Develop Licensed Products in the Field for the purpose of Commercializing Licensed Products in the Field in the Territory. Company will use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory. The Parties shall establish various Committees as set forth in Article 3 of this Agreement to oversee and/or coordinate the Development of Licensed Products in the Field and oversee the Commercialization of Licensed Products in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in Article 16, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to effectively and efficiently Develop and Manufacture Licensed Products in the Field and for Company (and, if agreed to by Company or set forth in the Plans, Regeneron) to effectively and efficiently Commercialize the Licensed Products in the Field in the Territory under this Agreement.

2.2 Compliance With Law. Both Company and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in an effort to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making

of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Existing Licenses and the New Licenses to which it is a party and to notify the other Party of any terms or conditions in any such Existing License or New License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Moreover, each Party shall take all actions reasonably necessary to ensure the other Party's ability to comply with (i) any such Existing License or New License (including any such terms and conditions with which such Party is required to comply as a sublicensee), and (ii) any such material agreement entered into pursuant to a Plan. Neither Party may terminate or amend any Existing License, New License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.

2.5 Plans. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.

2.6 Limitation on Exercise of Rights Outside of Collaboration.

(a) During the Term, except as set forth in this Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Product in the Field in the Territory, except pursuant to this Agreement. For the avoidance of doubt, nothing in the preceding sentence or elsewhere in this Agreement shall limit or restrict either Party's right to research, develop, make, have made, use, sell, offer to sell, have sold, import and export its Products outside the Field, including, without limitation, Regeneron's and Aventis' activities under the Aventis Agreement.

(b) If a Party (the "Proposing Party") presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then the Proposing Party may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the Development Plans; provided, however, the Proposing Party must first present the proposed protocols and clinical trial designs to the other Party for approval, such approval not to be unreasonably withheld or delayed and, for other than

Non-Approval Trials or trials conducted solely for purposes of obtaining Approvals in the Excluded Territory, shall also present to the other Party the related budgets for Clinical Supply Costs and Out-of-Pocket Costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). The other Party's representatives on the JDC may only disapprove any such protocols or clinical trial designs for material safety reasons. If, in compliance with this Section 2.6(b), the other Party does not approve any such protocols or clinical trial designs for material safety reasons, the Proposing Party may not proceed with the proposed clinical trials unless and until the dispute has been resolved as provided in Section 3.10(b) and, if necessary, Section 10.4. In the event that the Proposing Party conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article 4 of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to the Proposing Party with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trials to support an Approval in the Territory, then the other Party shall be required to reimburse the Proposing Party for [**********] of the actual Out-of-Pocket Costs and Clinical Supply Costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to the other Party pursuant to this Section 2.6(b) (if applicable) and the other terms of this Agreement. Nothing in this Section 2.6(b) shall permit Regeneron to make a Registration Filing in the Territory or seek an Approval in the Territory based on any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b), and publication of all data and results thereof shall be subject to Article 16.

(c) If Company determines that one of its or one of its Affiliates' internal product candidates constitutes a Product in the Field or if Company or its Affiliate acquires rights to a Product in the Field in the Territory from a Third Party, Company shall promptly present a proposal to the JDC to include such Product in the Collaboration based on the terms of this Agreement, and, as part of such presentation, shall provide the JDC with all information with respect to such Product reasonably available to Company and material to a decision by Regeneron's representatives on the JDC as to whether to approve the inclusion of such Product in the Collaboration. If Regeneron's representatives on the JDC, in their sole discretion, approve such inclusion of such Product in the Collaboration as a Licensed Product, then such Product shall be included in the Collaboration on the terms of this Agreement (such Products being referred to as "Company Products"). If Regeneron's representatives on the JDC, in their sole discretion, do not approve such inclusion of such Product in the Collaboration, then, for such Products arising from Company's or its Affiliates' internal research and development activities or to which Company or its Affiliates acquire rights, Company or its Affiliates may continue to Develop such Product in the Field in the Territory up to the completion of Phase 2 Trials, at which time Company shall present to Regeneron's representatives on the JDC the available clinical data with respect to such Product for the approval by Regeneron's

representatives on the JDC of inclusion of such Product in the Collaboration as a Licensed Product under the terms of this Agreement. If Regeneron's representatives on the JDC do not, in their sole discretion, approve the inclusion of such Product in the Collaboration on the terms of this Agreement, then Company or its Affiliates may license or otherwise transfer rights to such Product in the Territory in the Field to a Third Party without any further consideration or payments to Regeneron. However, neither Company nor any of its Affiliates may participate in the further Development or Commercialization of such Products in the Field in the Territory. For the avoidance of doubt, any modification, derivative or new formulation of a Regeneron Product Developed by either Party shall be considered a Regeneron Product and not a Company Product.

2.7 Excluded Territory Activities. Notwithstanding that a Company Product or a Regeneron Product is deemed a Licensed Product hereunder, and for the avoidance of doubt, Company shall have the exclusive right and authority, in its discretion, to exploit Company Products in the Field in the Excluded Territory and Regeneron shall have the exclusive right and authority, in its discretion, to exploit Regeneron Products in the Field in the Excluded Territory, in each case, subject only to the terms of this Agreement that expressly apply to Licensed Products in the Field in the Excluded Territory. Each Party agrees to reasonably communicate and consult with the other Party (through the JDC or the other Party's representatives on the JDC, with respect to Development activities, and through the JCC or the other Party's representatives on the JCC, with respect to commercialization activities) on material Development and commercialization activities relating to Licensed Products in the Field in the Excluded Territory. Notwithstanding the foregoing or any other provision in this Agreement, neither Party nor any Committee shall have the right or authority to manage or control the internal operations of the other Party or to approve, modify, impede or delay any of the other Party's commercialization or Development plans or activities for its Products in the Excluded Territory (other than as contemplated under or in connection with the Global Development Plan). Each Party shall reasonably inform the JDC or the JCC or the other Party's representatives on the JDC or JCC, as applicable, of (a) all material clinical and regulatory matters directly relating to its Products in the Excluded Territory, whether or not addressed in the Global Development Plan, and (b) any other Development or commercialization activities directly relating to its Products in the Excluded Territory to the extent such matters or activities would be reasonably expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Territory. To the extent any of the foregoing matters or activities in the Excluded Territory are undertaken pursuant to the Global Development Plan, each Party shall comply with the Global Development Plan; otherwise, the Party Developing and/or commercializing its Product(s) in the Excluded Territory shall consider in good faith all comments of the JDC and the JCC (or the other Party's representatives on the JDC or JCC) with respect to such matters and activities.

ARTICLE III
MANAGEMENT

3.1 Committees/Management.

(a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Joint Steering Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Effective Date, the Parties will establish the JSC, which shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program; for the Manufacture of Licensed Products in the Field for use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.10 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager ("Alliance Manager") to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually

review and approve the Development Plan(s), Manufacturing Plan(s) and Territory Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC as the JSC deems appropriate and (v) consider and act upon such other matters as are specified in this Agreement or otherwise agreed to by the Parties.

3.3 Joint Development Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Effective Date, the Parties will establish the JDC. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the Development of Licensed Products in the Field as part of an integrated worldwide Development program; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Development Plan(s) (and related Development Budget(s)) and (iii) to oversee the implementation of the Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that each Party must appoint, as one of its representatives on the JDC, its Project Manager and provided further, that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) Specific Responsibilities. In particular, subject to Section 2.7, the JDC shall be responsible for:

(i) advising the JSC on the overall global Development strategy for the Licensed Products in the Field;

(ii) facilitating an exchange of Development data between the Parties and developing and updating the Development Plans (and related Development Budgets), as described in Sections 5.2 and 5.3, for final approval by the JSC;

(iii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of, and compliance with, the Development Plans (including the Development Budgets);

(iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;

(v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans; advising on material clinical and regulatory matters and other Development activities in the Excluded Territory that are reasonably expected to

materially adversely affect, or have a material impact on, the Development of Licensed Products in the Territory; and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Development Plans and for Non-Approval Trials;

(vi) reviewing and approving proposed target Licensed Product labeling and reviewing, and to the extent set forth herein approving, proposed changes to Product labeling with respect to Licensed Products in the Field in accordance with Section 7.2(f) ;

(vii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;

(viii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;

(ix) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field;

(x) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan; and

(xi) considering and acting upon such other matters as are specified in this Agreement or by the JSC.

3.4 Joint Commercialization Committee.

(a) Formation; Composition and Purpose. Within twenty (20) days after the Effective Date, the Parties will establish the JCC. The purpose of the JCC shall be (i) to develop and propose to the JDC and JSC the strategy for the Commercialization of Licensed Products in the Field in the Territory; (ii) to discuss and advise on certain commercialization activities for the Licensed Products in the Excluded Territory to the extent contemplated in Section 2.7; (iii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Territory Commercialization Plan (and related Territory Commercialization Budget); (iv) to develop (or oversee the development of), review and annually update and approve the Country Commercialization Plans (and related Country Commercialization Budgets) and (v) to oversee the implementation of the Territory Commercialization Plan and the

Commercialization operational aspects of the Collaboration. The JCC shall be composed of at least two (2) senior executives of each Party.

(b) JCC Responsibilities. In particular, subject to Section 2.7, the JCC shall be responsible for:

(i) recommending to the JSC whether a single brand will be used for Commercialization of Licensed Products for one or more indications throughout the Excluded Territory and the Territory ("Global Brand"). If the JCC agrees that a Global Brand(s) for the Licensed Products is desirable,[**********];

(ii) developing and proposing to the JSC the strategy for the Commercialization of the Licensed Products in the Field in the Territory;

(iii) commencing no later than three (3) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing, and updating at least annually, the Territory Commercialization Plans (and related Territory Commercialization Budgets) for final approval by the JSC and (B) approving the Country Commercialization Plan(s) (and related Country Commercialization Budget(s));

(iv) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan for review by the JSC;

(v) developing and updating, as necessary [**********] (collectively, the items referred to in this paragraph (v) shall be referred to as the "Marketing Guidelines") as part of the Territory Commercialization Plan;

(vi) developing target profiles for the Licensed Products in the Field;

(vii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of and compliance with the Territory Commercialization Plans (including the Territory Commercialization Budgets) and Country Commercialization Plans (including the Country Commercialization Budgets), including ensuring that country specific launch plans in the Territory are consistent with the Marketing Guidelines;

(viii) establishing, as necessary, sub-committees of the JCC;

(ix) if the Parties agree to use a Global Brand, selecting a Product Trademark for Licensed Products in the Field in accordance with

Section 11.2 and giving guidance on trade dress in the Field (**********);

(x) if the Parties agree to use a Global Brand, [**********]

(xi) developing and implementing plans and policies regarding journal and other publications with respect to Licensed Products in the Field in concert with the JDC;

(xii) allocating the appropriate cost for Commercialization activities that support the Licensed Products in the Field in the Territory and the Excluded Territory as Other Shared Expenses and/or Shared Promotion Expenses, if applicable, in accordance with this Agreement and assigning responsibilities and approving budgets for such activities;

(xiii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;

(xiv) consulting on all commercialization activities for Licensed Products in the Field in the Excluded Territory that are reasonably expected to materially adversely affect, or have a material impact on, the Commercialization of Licensed Products in the Territory in accordance with, and subject to, Section 2.7 and Section 6.5; and

(xv) considering and acting upon such other matters as are specified in this Agreement or by the JSC or JDC.

3.5 Other Committees. Within ten (10) days after the Effective Date, the Parties will establish the JFC, which shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article 9 and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC and the JCC, as needed.

3.6 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Company. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Company. Each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue draft minutes of each meeting within seven (7) days thereafter and final minutes within thirty (30) days thereafter.

3.7 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than every Quarter during the Term. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of the Products (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Day's prior written notice, except that emergency meetings may be called with at least one (1) Business Day's prior written notice.

3.8 Decision-Making. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.

3.9 Project Manager. Each of Company and Regeneron shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Project Manager ("Project Manager"). Each Project Manager will be responsible for:

(a) coordinating the various functional activities of Company and Regeneron, as appropriate, in developing and executing strategies and Plans for the Licensed Products in the Field in an effort to ensure consistency and efficiency;

(b) providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization regarding key strategy and Plan issues, as appropriate, including facilitating review of external corporate communications; and

(c) identifying and raising cross-country, cross-Party and/or cross-functional disputes to the appropriate Committee in a timely manner.

3.10 Resolution of Governance Matters. As provided in Section 10.2, this Section 3.10 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible:

(i) in the case of any matter which cannot be resolved by the JDC, JCC, JFC or any other committee established by the JSC, at the request of either Party, such matter shall promptly, and in any event within five (5) Business Days (or one (1) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution;

(ii) in the event a unanimous vote on any matter cannot be obtained at the JSC within five (5) Business Days after referral to it pursuant to (i) above, except as set forth in (iii) below, Company shall have the deciding vote with respect to those matters described in [**********,]and Regeneron shall have the deciding vote with respect to those matters described in [**********]. Neither Party shall have the deciding vote with respect to matters described in [**********]. For the avoidance of doubt, [**********]

(iii) notwithstanding the above, and subject to Section 7.2(f), if either Party (the "First Party") [**********] then such dispute shall be resolved in accordance with the dispute resolution procedures set forth in Section 3.10(b); provided, however, that the dispute resolution procedures set forth in Section 3.10(b) shall not apply and the terms of subsection (ii) above shall apply (and thus, the final decision of the Party authorized to cast the deciding vote shall be final and binding on the First Party) if [**********].

(b) Referral to Executive Officers. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, and one Party is not expressly allocated decision making authority over the matter as set forth in this Agreement, then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which, except for Legal Disputes (unless as jointly agreed by the Parties), either Party may by written notice to the other Party require the specific issue in dispute to be submitted for resolution by an Expert Panel pursuant to Section 10.4, if such dispute is with respect to a Technical Development Matter.

(c) Interim Budgets. Pending resolution by the Executive Officers of any referred dispute under Section 3.10(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use

Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.10(c).

(d) Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

ARTICLE IV
LICENSE GRANTS

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.5) and any Existing License or New License to which Regeneron is a party, Regeneron hereby grants to Company (a) the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop, import and export Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, subject to Regeneron's right to supply Licensed Products to Company, as contemplated by this Agreement. Company will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.3. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Regeneron is a party, Regeneron also grants to Company the nontransferable (except as permitted by Section 20.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Regeneron Excluded Territory Intellectual Property to make, have made, use, sell, offer to sell, have sold, import or export Company Products for use in the Field in the Excluded Territory.

4.2 Company License Grants. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-exclusive (with Company and its Affiliates) right and license under the Company Intellectual Property to make, have made, develop, use, import and export Licensed Products for use in the Field in the Territory. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company also grants to Regeneron the nontransferable (except as permitted by Section 20.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Company Excluded Territory Intellectual Property to make, have made, use, sell, offer to sell, have sold, import or export Regeneron Products for use in the Field in the Excluded Territory.

4.3 Sublicensing. Unless otherwise restricted by any Existing License or New License, Company will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Company may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any Existing License or New License, Regeneron will have the right to sublicense any of its rights under the first sentence of Section 4.2 only with the prior written consent of Company, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Company's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article 16, and will include, with respect to a Sublicensee of Company, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Company on the same basis as if such sales were Net Sales by Company. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the Territory Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have a materially adverse effect on Regeneron or any of its Affiliates or any Regeneron Intellectual Property, then Regeneron may cause Company or its Affiliate to exercise, and the Company or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and Regeneron, at the option of Regeneron, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Company will forward to Regeneron a complete copy of each fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

4.4 No Implied License. Except as expressly provided in this Article 4 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.5 Retained Rights. With respect to the licenses granted under this Article 4, Regeneron reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, (a) the right to make, have made, distribute, import, export and use Regeneron Products in the Field in the Territory exclusively for Development purposes, and (b) the right to Manufacture and, if agreed to by Company or set forth in any Plans, the right to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Regeneron retains all rights in Regeneron

Intellectual Property, Regeneron's interest in the Joint Inventions and Regeneron Products not expressly licensed hereunder, including, without limitation the right (i) to exploit Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions to make, have made, use, sell, offer to sell, have sold, import or export Products for use outside the Field; (ii) to exploit Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions to make, have made, use, sell, offer to sell, have sold, and import and export Products for use in the Field in the Excluded Territory and (iii) to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

4.6 Right of Negotiation for Excluded Territory. In the event that Regeneron desires to enter into a license or co-promotion arrangement with a Third Party (other than with an Affiliate, distributor or contract sales force) with respect to commercialization of the Regeneron Products in the Excluded Territory, Regeneron shall grant Company a first right of exclusive negotiation for such commercialization rights. If Regeneron desires to enter into such a commercialization arrangement, Regeneron shall give Company written notice. Company shall have [**********] to determine and to notify Regeneron in writing whether Company desires to negotiate such a commercialization arrangement. Failure to provide written notice to Regeneron within such [**********] period shall be deemed to be a rejection of Regeneron's offer to negotiate for such commercialization rights. If Company rejects Regeneron's offer to negotiate for such commercialization rights, or if Company accepts Regeneron's offer to negotiate for such commercialization rights but the Parties are unable to reach an agreement on such commercialization arrangement, after negotiating in good faith, within [**********] of the date Regeneron notified Company of its desire to enter into such commercialization arrangement, then Regeneron shall have no further obligation to Company with respect to the Regeneron Products in the Excluded Territory.

ARTICLE V
DEVELOPMENT ACTIVITIES

5.1 Development of Licensed Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices. Regeneron may conduct separate Development activities to support Regeneron Products in the Excluded Territory, and Company may conduct separate Development activities to support Company Products in the Excluded Territory, in each case, subject to the conditions and requirements set forth herein, including, without limitation, Section 2.6(b).

5.2 Development Plans. The JDC shall prepare and update Development Plans for Licensed Products in the Field under this Agreement for approval by the JSC. Except for the first Global Development Plan incorporating the Initial Development Plan referred to below in this Section 5.2, an updated Global Development

Plan (and, if applicable, Territory Development Plan) will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Development Plan will set forth the plan for Development of each Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for the Licensed Products in the Field in the Territory and, subject to Section 2.7, the Excluded Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers to the extent provided by the applicable Development Plan. Each Development Plan will be reviewed and informally updated by the JDC not less frequently than every six (6) months for the ensuing three (3) year period. The activities agreed to by the Parties (together with the associated estimated budget) as set forth on Schedule 5 shall constitute the initial plan for the Development of Licensed Products in the Field under this Agreement (the "Initial Development Plan"). No later than sixty (60) days after the Effective Date, the JDC will meet to finalize the first Global Development Plan (which, as provided above, shall incorporate, or be substantially consistent with, the Initial Development Plan). Until the first Global Development Plan is approved by the JSC, the Parties will Develop the Licensed Products in the Field under this Agreement in accordance with the Initial Development Plan, unless otherwise agreed to by the JSC. Unless otherwise agreed to by the JDC, each update to the Development Plan(s) shall include the activities and timelines described in or referred to in the Initial Development Plan until the activities described therein are completed in a timely manner.

5.3 Development Budgets. The Territory Development Plan shall include the Territory Development Budget and the Global Development Plan shall include the Global Development Budget (each individually, a "Development Budget" and both collectively, the "Development Budgets") and the Development Budgets shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Development Plans in accordance with this Agreement. Amendments and updates to any Development Budgets shall not be effective without the approval of the JSC. In the event that, during any Contract Year (the "First Year"), any Development activity expressly provided for in the approved Development Budget to be completed during such First Year is not completed during such First Year (to the extent incomplete, an "Incomplete Activity") and the full expense budgeted for such activity for such First Year is not incurred (to the extent not incurred, a "Non-Incurred Amount"), then such Incomplete Activity shall be completed during Contract Years following such First Year (the "Succeeding Year(s)") and the Non-Incurred Amount shall be included in the Development Budget for such Succeeding Year(s) as set forth in the following sentence. If the Development Budget for such Succeeding Year(s) has not yet been approved by the JSC, then the Non-Incurred Amount shall be included in the proposed Development Budget for such Succeeding Year(s) without otherwise limiting any other Development activities or any amounts related thereto, unrelated to the Incomplete Activity, which, pursuant to the Development Plan, would have been performed during such Succeeding Year, and if the Development Budget for the Succeeding Year(s) has been approved by the JSC, then the Development Budget for such Succeeding Year (s) shall be revised automatically to include the Non-Incurred Amount.

5.4 Development Reports. Within forty-five (45) days after the end of each Quarter, Regeneron and Company shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter and shall be in such form, format and of such level of detail as approved by the JFC. At the next JDC meeting held following such forty-five (45) day period, the JDC will approve the final Development Costs which will be used in the calculation of the Global Development Balance.

5.5 Review of Clinical Trial Protocols. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by either Party pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials meeting established criteria. In no event will such procedures require more than ten (10) Business Days for the JDC to accept or reject a proposed protocol and/or clinical trial design for a clinical study to be conducted solely for purposes of obtaining an Approval in the Excluded Territory.

ARTICLE VI
COMMERCIALIZATION

6.1 Commercialization of Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC and in accordance with the Territory Commercialization Plan and the Country Commercialization Plans. Except as set forth in this Agreement, Company shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory.

6.2 Territory Commercialization Plan. The Territory Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Territory Commercialization Plan will be prepared by Company, with Regeneron's participation and input with respect to the portions of such Plan directly applicable to the Major Market Countries, and submitted to the JCC for review and approval. Once approved by the JCC, the Territory Commercialization Plan will be presented to the JSC for review and approval at least [**********] before the Anticipated First Commercial Sale in the Territory. The Territory Commercialization Plan for each subsequent Contract Year shall be updated by the JCC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year. Each Territory Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(a) the overall strategy for Commercializing Licensed Products in the Field in the Territory, including Licensed Product target product profiles, branding, positioning, promotional materials and core messages;

(b) subject to applicable Law, Licensed Product pricing guidelines in the Field in the Territory;

(c) the Territory Commercialization Budget;

(d) anticipated launch dates for applicable countries in the Territory;

(e) any global Commercialization activities that are designed to benefit the Licensed Product in the Field in both the Territory and the Excluded Territory (including, without limitation, such activities that relate to global branding, global market research, Licensed Product websites and certain publication strategies);

(f) market and sales forecasts for the Licensed Products in the Field in the Territory in a form to be agreed between the Parties;

(g) strategies for the detailing and promotion of Licensed Products in the Field in the Territory, including recommended sales force sizes in the countries in the Territory;

(h) anticipated major advertising, public relations and patient advocacy programs for Licensed Products in the Field in the Territory;

(i) reimbursement and patient assistance, including [**********];

(j) post-marketing clinical trials to support Commercialization of Licensed Products in the Field in the Territory which [**********], including any such clinical trials sponsored by Third Parties using Licensed Product supplied by the Parties ("Non-Approval Trials");

(k) proposed use of Third Party sales representatives, Sublicensees and/or distributors in any country in the Territory;

(l) target incentive product weighting and performance goals for sales representatives detailing the Licensed Products in the Field in the Territory; and

(m) all other Marketing Guidelines.

6.3 Country Commercialization Plans. Each Country Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Country Commercialization Plan for each Major Market Country will be prepared by Company, with Regeneron's participation and input, and approved by the JCC at least [**********] before the Anticipated First Commercial Sale in the applicable Major Market Country. The Country

Commercialization Plan for each subsequent Contract Year shall be updated and approved by the JCC at least two (2) months prior to the end of the then current Contract Year. Each Country Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(a) the overall strategy for Commercializing Licensed Products in the Field in the Major Market Country, including Licensed Product branding, positioning, promotional materials, core messages, pricing strategies and competitive analyses;

(b) the Country Commercialization Budget;

(c) anticipated launch dates for the Licensed Product in the Field in the Major Market Country;

(d) market and sales forecasts for the Licensed Products in the Field in the Major Market Country in a form to be agreed between the Parties;

(e) strategies for the detailing and promotion of Licensed Products in the Field in the Major Market Country, including sales force and medical affairs field force sizes, the number and type of Licensed Product details to be performed by Company sales representatives and target opinion leaders in the Major Market Country;

(f) FTE requirements and Shared Promotion Expenses to fulfill the requirements of the Country Commercialization Plan;

(g) advertising, patient advocacy programs, professional symposia, public relations, marketing, sales and promotion efforts for Licensed Products in the Field in the Major Market Country;

(h) reimbursement and patient assistance, including [**********]; and

(i) Non-Approval Trials (based on JDC approved protocols), [**********] in support of the Licensed Products in the Field in the Major Market Country.

6.4 Commercialization Activities; Sharing of Commercial Information.

(a) Company (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Territory Commercialization Plan and the Country Commercialization Plans. Without limiting the foregoing, Company will, as necessary, build, train and apply a field force in the Territory necessary to

Commercialize the Licensed Products in the Field in the Territory in accordance with the Territory Commercialization Plan and Country Commercialization Plans.

(b) Company will use reasonable efforts to provide Regeneron with full access to Company information directly relating to the Commercialization of the Licensed Products in the Field in the Territory, including, without limitation, information relating to anticipated launch dates, the development of sales targets by customer segment and territory, key market metrics, market research, sales forecasting and modeling, sales, prescription and patient data, reimbursement and pricing matters, and field force plans, goals, incentives and training.

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information from the Territory or the Excluded Territory, as the case may be.

(d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.

6.5 Product Pricing and Pricing Approvals in the Territory. [**********]. For the avoidance of doubt, (i) Regeneron shall have sole authority for determining and establishing the price and terms of sale (including any rebates or discounts) of Regeneron Products in the Excluded Territory and Company shall have sole authority for determining and establishing the price and terms of sale (including any rebates or discounts) of Company Products in the Excluded Territory.

6.6 Sales and Product Distribution in the Territory; Other Responsibilities. Company (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Company (or its Affiliate) also shall be responsible for (a) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (b) handling all returns of Licensed Product sold under this Agreement and (c) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory. If Licensed Product sold in the Field in the Territory is returned to Regeneron, it shall promptly be shipped to a facility designated by Company. If Regeneron Product sold in the Excluded Territory is returned to Company, it shall promptly be shipped to a facility designated by Regeneron. If Regeneron receives an order for Licensed Product in the Field in the Territory (or Company receives an order for Regeneron Product in the Field in the Excluded Territory), the Party erroneously receiving the order shall refer such orders to the other Party.

6.7 Commercialization Efforts. Company's sales representatives in the Territory shall provide the FTE effort and promote and detail the Licensed Products in the Field in accordance with the approved Country Commercialization Plan (if applicable), Territory Commercialization Plan and all applicable Laws. Company shall, at its own expense, comply with the training plan contained in any Country Commercialization Plan.

Beginning in the Quarter of the First Commercial Sale in each Major Market Country, Company will provide Regeneron on a quarterly basis with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Company for its internal management purposes. Company (through its local Affiliates where appropriate) shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the determination of Sales Force Cost and Medical Affairs Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

6.8 Contract Sales Force. Company shall not use the services of a sales representative employed by a Third Party without Regeneron's prior written consent. Company will be responsible for (a) all costs associated with retaining any such contract sales force in excess of the expected Sales Force Cost if Company provided its own field force and for such Third Party's compliance with this Agreement, (b) ensuring such contract sales force's compliance with all applicable Laws and (c) ensuring that sales representatives in such contract sales force have minimum skill levels customary for sales representatives in the Field at major pharmaceutical companies in such country.

6.9 Promotional Materials.

(a) Company will be responsible, consistent with the Marketing Guidelines, the Territory Commercialization Plan and the Country Commercialization Plans (as applicable), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the Territory. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Company for use in the Territory. (b) Company shall use its own corporate name and/or logo on Promotional Materials and Licensed Product labels in connection with Commercialization of Licensed Products in the Territory, unless otherwise mutually agreed by the Parties.

(b)The Parties shall jointly own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.

6.10 Promotional Claims/Compliance. Neither Company nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), Company and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.

6.11 Restriction on Bundling in the Territory. If Company or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Company agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed

Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer or (b) is inconsistent with the Collaboration Purpose.

6.12 Inventory Management. Company shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.13 Medical and Consumer Inquiries. Company shall be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Licensed Products in the Field in the Territory. The Parties will work together to formulate responses to the major inquiries, which shall be used, if possible, by Company in the Territory and Regeneron in the Excluded Territory. If Regeneron receives questions about Licensed Products in the Field in a country in the Territory, it shall refer such questions to Company, and Company shall be responsible for responding thereto. If Company receives a question about Regeneron Products in the Field in a country in the Excluded Territory (or about any Regeneron Product outside the Field), it shall refer such questions to Regeneron, and Regeneron shall be responsible for responding thereto.

6.14 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Product in the Field may be marketed in such country.

6.15 Post Marketing Clinical Trials. Subject to the provision of this Agreement, the Parties shall comply with any clinical trial obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

6.16 Activities outside the Collaboration. During the Term, neither Party nor any of its respective Affiliates, either alone or through any Third Party, shall Develop or Commercialize a Product in the Field in the Territory except as set forth in this Agreement. In the event that (a) Regeneron terminates this Agreement for any reason or (b) Company terminates this Agreement for any reason other than pursuant to Section 19.3 or Section 19.4, then [**********], Company (nor its Affiliates or Sublicensees) shall not, directly or indirectly, Commercialize any Products in the Field in any part of the Territory. In the event that Company terminates this Agreement pursuant to Section 19.3 or Section 19.4, [**********] Regeneron (nor its respective Affiliates or Sublicensees under this Agreement) shall not, directly or indirectly, Commercialize any Products in the Field in any part of the Territory other than Regeneron

Products as to which, as of the date notice of such termination is received by Regeneron, Regeneron has ownership of, or a license to. A Party shall not be considered in breach of this Section 6.16 solely by reason of the acquisition by such Party of a Person (i) if such Party includes the offending Product(s) in the licenses granted to the other Party pursuant to this Agreement or (ii) if prior to the closing of such acquisition, the acquiring Party commits in writing to the other Party that, promptly following the closing of such acquisition, it will divest itself of the offending rights and/or activity, and the acquiring Party uses Commercially Reasonable Efforts to pursue such divestiture, and in the event that such divestiture is not completed within six (6) months of the closing of such acquisition, the acquiring Party ceases all Development, Manufacturing and/or Commercialization, as applicable, of the offending Product(s) in the Field or includes the offending Products(s) in the licenses granted to the other Party pursuant to this Agreement.

6.17 Restriction on Commercialization Activities. Company agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing Regeneron Products outside the Field, and, in particular, engaging in any advertising, promoting or marketing of Regeneron Products aimed at uses outside the Field. Without limiting the foregoing, it is agreed that the Parties shall use Commercially Reasonable Efforts to [**********] and each Party shall use Commercially Reasonable Efforts to [**********]. Company further agrees that it shall refrain from pursuing a policy of directly or indirectly selling, advertising, promoting or marketing Licensed Products that it is Commercializing hereunder in the Field in the Territory for sale in the Excluded Territory. Each Party will use reasonable efforts to prevent the unauthorized importation of Licensed Products into the Territory or Excluded Territory, as the case may be.

6.18 Exports from the Territory to the Excluded Territory.

(a) Company shall supply the [**********] with Licensed Products in quantities that are appropriate to the size of such market (not including cross-border sales).

(b) The Parties shall discuss, as appropriate from time to time, through their respective representatives on the JSC, any concerns either Party may have with respect to the entry of Licensed Products into the Excluded Territory from the Territory, including [**********] ("Parallel Trade Concern").

(c) No later than ninety (90) days after Regeneron raises a Parallel Trade Concern, the Parties hereby agree to negotiate in good faith to determine a method for the calculation of [**********] (the "Parallel Unit Sales"). Such Parallel Unit Sales shall be determined based on available data, as agreed by the Parties, measuring [**********]. Out-of-Pocket Costs associated with obtaining the data required to meet Company's obligations hereunder shall be treated as Shared Promotion Expenses.

(d) Within fifteen (15) days after the end of any Contract Year in which Regeneron raises a Parallel Trade Concern, Company shall provide a detailed written report, which shall include copies of all data used to generate such report (the "Parallel Trade Report"), to Regeneron. The Parallel Trade Report shall [**********]

(e) Promptly following delivery of the Parallel Trade Report, the Parties will meet and make a good faith effort to agree upon [**********]

(f) Notwithstanding anything to the contrary contained herein, nothing contained in this Section 6.18 shall require any Party to take actions inconsistent with applicable Law.

ARTICLE VII
CLINICAL AND REGULATORY AFFAIRS

7.1 Ownership of Approvals and Registration Filings.

(a) Regeneron shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Development of Regeneron Products in the Field in the Excluded Territory under the Global Development Plan and (ii) with respect to any site license for its manufacturing facilities anywhere in the world, and shall have the rights and obligations set forth in this Article 7 with respect thereto.

(b) During the Term, Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Licensed Products in the Field in each country in the Territory and (ii) with respect to any site license for its manufacturing facilities anywhere in the world, and shall have the rights and obligations set forth in this Article 7 with respect thereto. Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, for any Company Products in the Field in the Excluded Territory with respect to the Development of Company Products under a Global Development Plan.

(c) The Lead Regulatory Party shall, as reasonably necessary to permit a Party to perform obligations under this Agreement, license, transfer, provide a letter of reference with respect to or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the Licensed Product in the Field in each jurisdiction as to

which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article 7. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for the Licensed Products in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.

(b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities, (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the world, including the Excluded Territory, and (iii) to comply with Laws with respect to the development, manufacture and/or commercialization of Products outside the Field. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory, and, subject to Section 2.7, with respect to the same in the Excluded Territory to the extent that such strategies, actions, and/or communications would reasonably be expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Field in the Territory.

(c) Subject to Sections 2.7 and 7.2(f), the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities that directly pertain to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including, without limitation, all annual and periodic safety reports for Licensed Products in the Field). Moreover, the Lead Regulatory Party shall consider in good faith requests from the other Party to have up to two (2) representatives from the other Party attend (but not participate) in all material, pre-scheduled meetings, telephone conferences and/or discussions with the Regulatory Authorities in the Territory or, to the extent such material meetings, telephone conferences and/or discussions pertain to the activities under the Global Development Plan, the Excluded Territory. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The

Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

(d) For the avoidance of doubt, nothing in this Section 7.2 entitles Company to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Regeneron Products in the Excluded Territory, except as they relate to the performance of the Global Development Plan. Subject to its obligations hereunder, Regeneron, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the Commercialization of Regeneron Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit, any Registration Filings for Marketing Approval for a Regeneron Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Regeneron Product.

(e) For the avoidance of doubt, nothing in this Section 7.2 entitles Regeneron to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Company Products in the Excluded Territory, except as they relate to the performance of the Global Development Plan. Subject to its obligations hereunder, Company, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the Commercialization of Company Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit any, Registration Filings for Marketing Approval for a Company Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Company Product.

(f) [**********].

7.3 Regulatory Coordination with Third Parties. Regeneron shall use Commercially Reasonable Efforts under the Aventis Agreement (a) to allow Company and its Affiliates to reference the filings, registrations, licenses and authorizations from or with any Regulatory Authority in connection with Regeneron's and Aventis' development, manufacture and commercialization of Products outside the Field to support the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory under this Agreement and (b) to coordinate the exchange of information (including, without limitation, information pertaining to pharmacovigilance, development, manufacture and commercialization) related to Licensed Products inside and outside the Field between Regeneron, Company and Aventis (or any other Third Party licensee of Regeneron engaged in the development, manufacture and/or commercialization of Licensed Products outside the Field) in order to ensure compliance with applicable Laws. It is agreed that (i) Regeneron and its Affiliates and licensees of Regeneron Products outside the Field (including, without limitation, Aventis) or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the

Regeneron Products to support their development, manufacture and commercialization of Regeneron Products outside the Field or outside the Territory and (ii) Company and its Affiliates and licensees of Company Products outside the Field or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the Company Products to support the development, manufacture and commercialization of Company Products outside the Field or outside the Territory. Company and Regeneron shall work in good faith to coordinate the exchange of information (including, without limitation, pharmacovigilance information) related to Products inside and outside the Field (and inside and outside the Territory) between Regeneron, Company and Aventis (or any other Third Party licensee of a Party engaged in the development, manufacture and/or commercialization of Products outside the Field or outside the Territory) in order to ensure compliance with applicable Laws. As between the Parties, Regeneron shall have the exclusive right to communicate with Regulatory Authorities with respect to Regeneron Products outside the Field and, subject to Section 2.7, in the Excluded Territory, and Company will have the exclusive right to communicate with Regulatory Authorities with respect to Company Products outside the Field and, subject to Section 2.7, in the Excluded Territory.

7.4 Regulatory Events. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority in the Territory or Excluded Territory, which:

(a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field in the Territory.

Information that shall be disclosed pursuant to this Section 7.4 shall include, but not be limited to:

(i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the

extent involving matters described in clauses (a), (b) or (c) of this Section 7.4;

(iii) receipt of a warning letter issued by a Regulatory Authority;

(iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and

(v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).

7.5 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints for its territory and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning drug safety surveillance and product complaint reporting in all countries in which the Licensed Products (both in the Field and out of the Field) are being developed, manufactured, or commercialized in the Territory or in the Excluded Territory. Without limitation to the foregoing, the Parties shall within ninety (90) days of the Effective Date execute a Pharmacovigilance Agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse drug experiences and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.

7.6 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

7.7 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

ARTICLE VIII
MANUFACTURING AND SUPPLY

8.1 Formulated Bulk Product Supply in the Field in the Territory. Subject to Regeneron's obligations under the Aventis Agreement, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements of Regeneron Product in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Company's prior written approval, such approval not to be unreasonably withheld or delayed, Company or Third Parties to Manufacture such Formulated Bulk Product. [**********.] The Formulated Bulk Product Manufactured by or on behalf of Regeneron will be billed to Company by Regeneron at the Manufacturing Cost.

8.2 Finished Product Supply in the Field in the Territory. The Parties, through the JSC, will identify which Party or Third Party will perform the filling, packaging, labeling and testing of the Formulated Bulk Product to supply Finished Product for Clinical Supply Requirements and Commercial Supply Requirements for use in the Field under this Agreement. The Finished Product Manufactured by or on behalf of a Party will be billed at the Manufacturing Cost to the other Party as a Development Cost or Commercial Supply Cost, as the case may be, in accordance with Schedule 1.

8.3 Supply Agreement. Within six (6) months after the Effective Date, the Parties shall enter into one or more clinical supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements, which shall contain terms consistent with this Agreement. At least [**********] prior to the Anticipated First Commercial Sale, the Parties shall enter into separate commercial supply agreements with respect to the quality assurance/quality control, forecasting, ordering and delivery of Clinical Supply Requirements and Commercial Supply Requirements after the First Commercial Sale, which shall contain terms consistent with this Agreement. Each supply agreement will include as an annex thereto a customary quality agreement containing terms and conditions regarding quality

assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

8.4 Manufacturing Plans. The Parties, through the JSC, will develop and update as necessary, the Licensed Product Manufacturing plan (the "Manufacturing Plan") providing for the Manufacturing (including testing and specifications), distribution, and forecasting of Clinical Supply Requirements under the Development Plans and Commercial Supply Requirements under the Territory Commercialization Plan, including, if applicable, the choice of Third Party manufacturers, fillers, packagers, and labelers. However, Regeneron will have the right to make all decisions with respect to Manufacturing Formulated Bulk Product for Regeneron Products, subject to Company's prior written approval, such approval not to be unreasonably withheld or delayed. Each Manufacturing Plan shall set forth the Licensed Product requirements over an ensuing period of at least three (3) Contract Years. The Manufacturing Plan will include [**********]. The Manufacturing Plan (including each annual update thereto) shall be approved by the JSC at least two (2) months prior to the end of the then current Contract Year, except that the initial Manufacturing Plan shall be approved by the JSC within four (4) months after the Effective Date. The Parties shall design Manufacturing Plans to ensure an adequate supply of Licensed Product and shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the approved Manufacturing Plans.

8.5 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product should be utilized. In case of Finished Product or Formulated Bulk Product shortages, available supplies will be allocated as between the Parties on a pro rata basis based on their forecasted requirements for Licensed Product in the Field in the Territory and the Excluded Territory over the relevant period; provided that priority shall be given to meeting supply requirements for countries in which Licensed Products are in the launch phase and that, if the shortage is due solely to a breach by Regeneron, Company's (and, if applicable, Regeneron's) reasonable requirements under the Plans will be filled first in advance of filling requirements for the Excluded Territory.

8.6 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article 8 or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of Licensed Products in the Field pursuant to

this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Aventis, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

ARTICLE IX
PERIODIC REPORTS; PAYMENTS

9.1 Upfront Payment and Milestone Payments.

(a) Within five (5) Business Days of the Effective Date, Company will pay to Regeneron the non-refundable, non-creditable amount of US $75,000,000 (which shall not be reduced by any withholding or similar taxes).

(b) In addition to the other payments contemplated herein, Company shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Company shall have five (5) Business Days from the receipt of an invoice from Regeneron related to the achievement of any such milestone to pay the corresponding amount to Regeneron, which, in each case, shall not be reduced by any withholding or similar taxes.

9.2 Development Costs.

(a) Regeneron shall be responsible for paying one hundred percent (100%) of the Development Costs incurred by it under the Global Development Plan in 2006. In 2007, (i) the Parties shall each pay fifty percent (50%) of the Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan up to a total of US $50,000,000, and (ii) Regeneron shall pay one hundred percent (100%) of Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan in excess of US $50,000,000, up to the amount budgeted for 2007 in the Initial Development Plan. In 2008, (i) the Parties shall each pay fifty percent (50%) of the Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan, up to a total of US $70,000,000, and (ii) Regeneron shall pay one hundred percent (100%) of Development Costs budgeted for in the Initial Development Plan and incurred under the Global Development Plan in excess of US $70,000,000, up to the amount budgeted for in 2008 in the Initial Development Plan (such amount paid by Regeneron pursuant to this clause (ii), together with the amount paid one hundred percent (100%) by Regeneron in 2007 pursuant to clause (ii) in the preceding sentence, being referred to as the "Aggregate Regeneron Payment Amount"). Notwithstanding the foregoing, [**********]. Commencing on January 1, 2009 and continuing during the Term, each of Company and Regeneron shall be responsible for paying fifty percent (50%) of all Development Costs incurred under the Global

Development Plan in accordance with the terms of this Agreement by or on behalf of Company, Regeneron and their respective Affiliates.

(b) Commencing on the Effective Date and continuing during the Term, Company shall be responsible for paying one hundred percent (100%) of the total Development Costs incurred under the Territory Development Plan in accordance with the terms of this Agreement by or on behalf of Company, Regeneron and their respective Affiliates.

(c) If Company desires to use efficacy data from a clinical trial conducted by or on behalf of Regeneron in the Excluded Territory (and outside the scope of the Global Development Plan) to support an application for Marketing Approval (including a new label claim) for a Licensed Product in the Field in the Territory, such trial shall be deemed to be part of the Global Development Plan and Company shall reimburse Regeneron for [**********] of the Development Costs incurred by Regeneron in connection with such trial, provided such clinical trial was previously presented to Company for inclusion in the Global Development Plan pursuant to Section 2.6(b). Nothing in this subsection (c) will require Company to reimburse Regeneron for such costs if the data is used solely as part of an annual report, periodic safety report or other regular filing required by a Regulatory Authority in the Territory or applicable Laws.

(d) If Regeneron desires to use efficacy data from a clinical trial conducted by or on behalf of Company pursuant to a Territory Development Plan to support an application for Marketing Approval (including a new label claim) for a Regeneron Product in the Field in the Excluded Territory, such trial shall be deemed to be part of the Global Development Plan and Regeneron shall reimburse Company for [**********] of the Development Costs incurred by Company in connection with such trial, provided such clinical trial was previously presented to Regeneron for inclusion in the Global Development Plan pursuant to Section 2.6(b). Nothing in this subsection (d) will require Regeneron to reimburse Company for such costs if the data is used solely as part of an annual report, periodic safety report, or other regular filing required by a Regulatory Authority in the Excluded Territory or applicable Laws.

9.3 Periodic Reports. Company and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;

(b) Within twenty (20) days following the end of each month, Company shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;

(c) Within forty-five (45) days following the end of each Quarter, Company shall deliver electronically to Regeneron a written report setting forth,

on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;

(d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses incurred by such Party in such Quarter, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;

(e) Within forty-five (45) days after the end of each Quarter commencing after the First Commercial Sale in a country in the Territory (or such earlier agreed upon calendar Quarter, if appropriate), Company shall provide to Regeneron, in electronic form, a Country Commercialization Report for each country in the Territory.

(f) Within forty-five (45) days following the end of each Quarter commencing after the First Commercial Sale in the Territory (or such earlier agreed upon calendar Quarter, if appropriate), each Party that has incurred any Shared Promotion Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Shared Promotion Expenses incurred by such Party in such Quarter;

(g) Within forty-five (45) days following the end of each Quarter, each Party (if applicable) shall deliver electronically to the other Party a written report setting forth Commercial Supply Costs incurred by such Party for such Quarter; and

(h) Within sixty (60) days following the end of each Quarter, Company shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article 9 and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.4 and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.3 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.4 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Company is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section 9.10, make such payment to Regeneron within ten (10) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section

9.10, make such payment to Company within ten (10) days after its receipt of such Consolidated Payment Report from Company. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Company shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any Existing License or New License (to the extent attributable to the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such Existing License and/or New License, as the case may be.

9.5 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.

9.6 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars at the average rate of exchange for the Quarter to which such payment relates, as reported in *The Bloomberg Professional*, a service of Bloomberg LP, or in the event *The Bloomberg Professional* does not have data available for the Quarter, then in *The Wall Street Journal* and by a method of conversion consistent with Company's customary and usual procedures used for currency conversion in its financial statements.

9.7 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in The *Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus [**********] (such sum being referred to as the "Default Interest Rate").

9.8 Taxes. Except with respect to the payments provided for in Section 9.1, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, Company agrees to make all lawful and reasonable efforts

to minimize any such taxes, assessments and fees and will claim on Regeneron's behalf the benefit of any available Treaty on the Avoidance of Double Taxation that applies to any payments hereunder.

9.9 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party (such request to occur not more than once every three (3) years for any country), the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Sales Force FTE Rate, Medical Affairs FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.10 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this Article 9, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.10(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

9.11 Budget Overruns. Notwithstanding anything to the contrary in this Agreement (including Section 3.10(a)(ii)), neither Party shall be required (a) to pay any Development Costs that are in excess of [**********] of the total amounts that are in the JSC approved Global Development Budget (or Territory Development Budget) for a Contract Year ("Development Overruns") or (b) to pay any Shared Promotion Expenses that are in excess of [**********] of the total amounts that are in the JSC approved Territory Commercialization Budget (or Country Commercialization Budget) for a Contract Year ("Commercialization Overruns"), unless such Development Overruns or Commercialization Overruns have been approved by both Parties' representatives on the JSC. Otherwise, the Party responsible for the Development and/or Commercialization activities that caused the overrun shall be responsible for bearing those costs and expenses, or, if both Parties contributed toward the overrun, they shall bear those excess expenses in the same proportion as their contributions to the overrun. Any such Development Overruns or Commercialization Overruns that are not approved by both Parties' representatives on the JSC shall not be included in the calculation of the Regeneron Reimbursement Amount, Global True-Up, Global Development Balance or Territory Profit Split, as applicable. For clarity, the Parties shall share, to the extent provided in this Agreement, Development Costs and Shared Promotion Expenses that are over the budgeted amounts in the Plans up to [**********] of the budgeted amounts.

ARTICLE X
DISPUTE RESOLUTION

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article 3 ("Governance Disputes") shall be resolved pursuant to Article 3 and, to the extent such matters constitute Technical Development Matters or a dispute referred to in Section 14.2(b), Section 10.4 (subject to, and without limitation of, the proviso in Section 3.10(a)(iii)), except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "Technical Development Matter" shall mean (a) any matter involving the Development of a Licensed Product in the Field, including the determination of clinical trial design and any Development or regulatory dispute referred to the Executive Officers pursuant to Section 3.10(a)(iii) and (b) any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).

10.3 Legal Disputes . The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.10(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.

10.4 Expert Panel

(a) In the event of a dispute between the Parties concerning a Technical Development Matter or a dispute referred to in Section 14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.10(b) (other than a Legal Dispute or any dispute concerning any proposed amendment to the Initial Development Plan), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4. Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. For disputes referred to the Expert Panel arising under Section 3.10(a)(iii), the Expert Panel in resolving the dispute shall balance the relative benefits and harm to each Party from the matter in dispute in connection with the applicable

Licensed Product in the Territory and Excluded Territory. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.

(b) Within fifteen (15) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.

(c) Within fifteen (15) days of the appointment of the second expert, the two-appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.

(d) Within seven (7) days of the appointment of the third expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel

agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution.

(e) In rendering the final decision (which shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.

10.5 No Waiver. Nothing in this Article 10 or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI
TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory and in the Excluded Territory, if applicable pursuant to Section 3.4(b)(i), unless such Product Trademark is prohibited by law in any country in the Territory. Each Licensed Product in the Field shall be promoted and sold in the Territory, and if applicable pursuant to Section 3.4(b)(i) in the Excluded Territory, under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Company (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory. It is understood and agreed that Regeneron shall own and retain all right, title and interest in the Product Trademark(s) for Regeneron Products,

together with all associated domain names and all goodwill related thereto in the Excluded Territory.

11.4 Prosecution and Maintenance of Product Trademark(s). Company will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Company elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Regeneron shall have the right to do so on behalf of Company for use with Licensed Products, subject to consultation and cooperation with Company.

11.5 License to the Product Trademark(s). Company hereby grants to Regeneron a co-exclusive license to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if agreed to by Company or set forth in any Plans, Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Company shall utilize the Product Trademark(s) only on approved Promotional Materials or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Company or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.

11.6 Use of Corporate Names. Company (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials exclusively related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product) in the Major Market Countries, unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field in the Major Market Countries as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and for a maximum period of three (3) years thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples solely to the extent necessary to exhaust the existing inventory of Licensed Product and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each

such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

ARTICLE XII
NEWLY CREATED INVENTIONS

12.1 Ownership of Newly Created Intellectual Property.

(a) Each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Company, its Affiliates, employees, agents and consultants are referred to herein as "Company Sole Inventions." Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Company or its Affiliate (or for which ownership vests in Company or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole ("Joint Inventions").

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article 4, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article 12 shall relieve a Party or its Affiliates of their obligations under Article 16 with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory and shall confer with and keep Company reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents in the Territory included in the Regeneron Patent Rights: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Company for review and comment a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and consider in good faith any comment from Company; (ii) Regeneron shall provide Company promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Company promptly

following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications and (iv) Regeneron shall consult with Company a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Company of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and, subject to any rights granted to Aventis under the Aventis Agreement, Company shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Regeneron's name, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Company that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret.

(b) Company shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Company Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Company shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents in the Territory included in the Company Patent Rights: (i) Company shall use Commercially Reasonable Efforts to provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Company and consider in good faith any comment from Regeneron; (ii) Company shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Company shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications and (iv) Company shall consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Company desires to abandon any Patent included in the Company Patent Rights in the Territory, Company shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Company Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Company's name, unless, with respect to any such Patent Applications that are unpublished, Company notifies Regeneron that

Company would prefer to maintain the subject matter of such Patent Application as a trade secret.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall use Commercially Reasonable Efforts to provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and consider in good faith any comment; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications

pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Company Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Company Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be shared by the Parties as part of Other Shared Expenses.

12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Company Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Patent Rights, by Company in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties. Regeneron may have certain obligations under Section 12.3 of the Aventis Agreement with respect to any such proceeding described in this Section 12.3(a) and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Company Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be shared by the Parties as part of Other Shared Expenses.

ARTICLE XIII
INTELLECTUAL PROPERTY LITIGATION

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual or suspected infringement of a Company Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property

right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any such actual or suspected infringement described in this Section 13.1 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) With respect to any infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Patent Rights, by Company in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party". The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall be shared equally by the Parties, subject to any obligations under any New License or Existing License.

(c) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) related to activities in the Field in the Territory shall be shared by the Parties as part of Other Shared Expenses.

(d) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent.

13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

13.3 Third Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any allegation described in this Section 13.3 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

(b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be shared by the Parties as Other Shared Expenses.

(c) For the avoidance of doubt, neither Party will enter into any settlement of any suit involving Licensed Products that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.

(d) License fees, royalties and other payments under Existing Licenses and New Licenses to the extent attributable to, and based on, the Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be shared by the Parties as Other Shared Expenses.

ARTICLE XIV
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its costs), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article 10. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than ten percent (10%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 16.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 GAAP/IAS/IFRS. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with GAAP or IAS/IFRS as generally and consistently applied.

ARTICLE XV
REPRESENTATIONS AND WARRANTIES

15.1 Due Organization, Valid Existence and Due Authorization. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article 4 hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Company additionally represents and warrants to Regeneron that it has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Regeneron Representations and Warranties. Regeneron additionally represents and warrants to Company that, as of the Effective Date:

(a) Regeneron has the right and authority to grant the rights and licenses granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that remain in effect which conflict with the rights and licenses granted herein;

(b) Except as set forth in Schedule 6, Regeneron is the sole owner of the Regeneron Patent Rights existing at the Effective Date, to Regeneron's knowledge, its title is free and clear of all liens, security interests and other encumbrances

(other than unilateral creditor filings, as to which this representation and warranty is made only to Regeneron's knowledge), and, except for the joint owner identified in Schedule 6 (and with respect to the Existing Licenses, the Third Party licensors referred to in Schedule 4), no Third Party has any right, title or interest in the Territory in the Field with respect to the Regeneron Patent Rights existing at the Effective Date;

(c) It has no knowledge that the making, using or selling of the VEGF Trap in the Field in the Territory would infringe any valid claims of the Patents of any Third Party in the Territory, nor does it have knowledge that any Third Party is infringing or misappropriating any of the Regeneron Intellectual Property;

(d) There are no judgments or settlements against or owed by Regeneron with respect to the Regeneron Intellectual Property owned by Regeneron;

(e) There are no claims, announced investigations, actions or other proceedings pending before or, to Regeneron's knowledge, threatened by any Regulatory Authority or other government agency with respect to the VEGF Trap, any Regeneron facility or, to Regeneron's knowledge, any other facility where the VEGF Trap is Manufactured, and Regeneron has not received written notice threatening any such claim, investigation, action or other proceeding;

(f) To the knowledge of Regeneron, the Development and Manufacture of VEGF Trap in the Field has been conducted by Regeneron and its Affiliates and its subcontractors in compliance in all material respects with applicable Laws, rules and regulations, and none of Regeneron or, to the knowledge of Regeneron, any of its Affiliates or subcontractors have received any notice in writing, or otherwise has knowledge of any facts, which have, or reasonably should have, led Regeneron to believe that any of the Registration Filings relating to the VEGF Trap in the Field are not currently in good standing with the FDA;

(g) To Regeneron's knowledge, neither Regeneron, nor any officer, employee or agent of Regeneron, has made an untrue statement of a material fact to any Regulatory Authority with respect to the VEGF Trap in the Field (whether in any submission to such Regulatory Authority or otherwise), or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the VEGF Trap in the Field;

(h) To Regeneron's knowledge, Regeneron and its employees, agents, clinical institutions and clinical investigators have materially complied with all FDA statutory and regulatory requirements with respect to VEGF Trap in the Field;

(i) Each Existing License is, to Regeneron's knowledge, in full force and effect as of the Effective Date. Regeneron has, to the extent contractually permitted, provided to Company, or allowed Company access to review, a true and complete copy of each Existing License. Regeneron will devote Commercially Reasonable Efforts to maintain the Existing Licenses in full force and effect and to perform its obligations thereunder and to keep Company informed of any material

development pertaining thereto that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement. Regeneron shall not, without the prior written approval of Company, (i) amend any provision of an Existing License that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement or (ii) make any election or exercise any right or option to terminate in whole or in part any Existing License to the extent such election or exercise would reasonably be expected to have a material adverse effect on Company's rights under this Agreement; and

(j) Regeneron has made available to Company, to the extent material, (i) written preclinical and clinical study results and protocols for the VEGF Trap in the Field, (ii) written communications to and from FDA with respect to the VEGF Trap in the Field, including but not limited to Registration Filings with the FDA and FDA minutes of meetings and telephone conferences, (iii) written FDA requests for data and studies with respect to the VEGF Trap in the Field and (iv) written reports of adverse drug experiences and other IND safety reports with respect to the VEGF Trap in the Field.

In reference to Section 15.3(c) above, the Parties acknowledge that they are aware of patents and pending patent applications owned by Genentech, Inc. that claim certain chimeric VEGF receptor compositions. Although Regeneron does not believe that the VEGF Trap infringes any valid claim in these patents or patent applications (if they were to issue), Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover the VEGF Trap. An adverse determination by a court in any such potential patent litigation would likely require the Parties to seek a license, which may not be available, or result in the Parties' inability to Develop, Manufacture or Commercialize the VEGF Trap in the Field in the Territory or in a damage award.

15.4 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) It will not during the Term grant any right or license to any Third Party in the Territory which would conflict with the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) Neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) In the course of the Development or Commercialization of a Licensed Product in the Field under this

Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE XVI
CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Company and Regeneron acknowledges (subject to the further provisions of this Article 16 and the provisions of Article 19) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Company, Party Information provided to it under the confidentiality agreement between the Parties dated July 6, 2006) is confidential and proprietary to such other Party. Furthermore, each of Company and Regeneron acknowledges (subject to the further provisions of this Article 16) that all New Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article 16, each of Company and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Company and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents or any other Person under its authorization; provided such employees, agents or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided above, the restrictions provided in this Article 16 shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance

pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

(c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to the Regeneron Products (including the Manufacture or use thereof) (i) to Aventis or any other Third Party licensee or contractor of Regeneron engaged in, and for use in connection with, the development, manufacture and/or commercialization of Regeneron Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, (ii) in connection with Regeneron's Development, Manufacture and/or Commercialization of Regeneron Products outside the Field, (iii) to any Third Party licensee or contractor of Regeneron engaged in the Development, Manufacture and/or Commercialization of Regeneron Products in the Excluded Territory under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, and (iv) to Governmental Authorities or Regulatory Authorities as required by Law.

(d) Notwithstanding anything provided above or elsewhere in this Agreement, Company and its Affiliates shall have the right to use and disclose any New Information directly related to Company Products (including the Manufacture or use thereof) (i) to any Third Party licensee or contractor of Company or any of its Affiliates' engaged in and for use in connection with the development, manufacture and/or commercialization of Company Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, (ii) in connection with Company's or any of its Affiliates' Development, Manufacture, and/or Commercialization of Company Products outside the Field, (iii) to any Third Party licensee or contractor of Company engaged in the Development, Manufacture and/or Commercialization of Company Products in the Excluded Territory under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a

term of at least five (5) years and (iv) to Governmental Authorities or Regulatory Authorities as required by Law.

16.2 Injunctive Relief. Each Party acknowledges that damages resulting from breach of this Article 16 would not be an adequate remedy and that, notwithstanding the provisions of Article 10, in the event of any such disclosure or any indication of an intent to disclose such information, a Party owning such Party Information (or each Party with respect to New Information) shall be entitled to seek, by way of private litigation, injunctive relief or other equitable relief, in addition to any and all remedies available at law or in equity, including the recovery of damages and reasonable attorneys' fees, and in any such action for equitable relief in a court of competent jurisdiction, the Parties will not assert as a defense that there is an adequate remedy at law.

16.3 Publication of New Information. During the Term, if either Company or Regeneron (the "Publishing Party") desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).

16.4 Other Publications. The Parties will mutually agree upon the contents of a joint press release with respect to the execution of this Agreement which shall be issued simultaneously by both Parties on the Effective Date. During the Term, Company and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration (e.g., that the Collaboration is ongoing in accordance with the terms of this Agreement). Except as required by a Governmental Authority or applicable Law (including the rules and

regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 16 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Company acknowledges that Regeneron as a publicly traded company is legally obligated to make timely disclosures of all material events relating to Licensed Products. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE XVII
INDEMNITY

17.1 Indemnity and Insurance.

(a) Company will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Company, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or

(ii) material breach by Company of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Company, its Affiliates and their respective officers, directors, employees, Sublicensees and agents ("Company Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Company Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Company or any other Company Indemnitee; or

(ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

(c) Subject to the last sentence of Section 19.6, in the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

(d) Company agrees to indemnify the Regeneron Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Company's or its Affiliates' or Sublicensees' Commercialization of Licensed Products in the Field in the Territory, except that Regeneron shall indemnify Company under Section 17.1(b) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee. Regeneron agrees to indemnify the Company Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Regeneron's or its Affiliates' or Sublicensees' commercialization of Regeneron Products in the Field in the Excluded Territory, except that Company shall indemnify Regeneron under Section 17.1(a) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Company or any other Company Indemnitee. Company agrees to indemnify the Regeneron Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Company's or its Affiliates' or Sublicensees'

commercialization of Company Products in the Field in the Excluded Territory, except that Regeneron shall indemnify Company under Section 17.1 (b) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee. Damages from product liability or other Third Party claims arising from the Development of any Licensed Product in the Field under this Agreement for which neither Party is entitled to indemnification under this Section 17.1 shall be treated as Development Costs.

(e) Immediately upon First Commercial Sale in the Territory, during the Term and for a period of five (5) years after the expiration of this Agreement or the earlier termination thereof, each Party shall use Commercially Reasonable Efforts to obtain and/or maintain (either directly or as a named insured on a Third Party insurance policy or policies), at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts, respectively, which are reasonable and customary for comparable products in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party; provided that Regeneron shall not be required to obtain or maintain such insurance in an amount greater than [**********] per incident and in the aggregate. Such product liability insurance or self-insured arrangements shall insure against personal injury, physical injury or property damage arising out of, for Regeneron, Manufacture of Licensed Products (if applicable) and sale, distribution or marketing of Regeneron Products in the Excluded Territory, and for Company, the sale, distribution or marketing of Licensed Products in the Territory.

(f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Company Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article 8; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article 8.

17.2 Indemnity Procedure. The Party entitled to indemnification under this Article 17 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(c) The amount of any Damages for which indemnification is provided under this Article 17 will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.

(d) If an Indemnified Party receives an indemnification payment pursuant to this Article 17 and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article 17 and (ii) the amount necessary to fully

and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article 17.

ARTICLE XVIII
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE XIX
TERM AND TERMINATION

19.1 Term/Expiration of Term.

(a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated as provided hereafter, shall end at such time as neither Party, nor either Party's Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent; provided, that if at any time during the Term Company loses the exclusive legal right to Commercialize Licensed Product in the Field in any Major Market Country, whether due to expiration of Regeneron Patent Rights or expiration of any statutory marketing exclusivity period for Licensed Product in such Major Market Country, the Parties shall meet to discuss and attempt to enter into an amendment to this Agreement for the purpose of simplifying the governance structure hereunder.

(b) Upon expiration of the Term, except as set forth in this Agreement, all licenses and rights with respect to Products shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause. Company may terminate this Agreement with respect to the entire Territory for all Licensed Products in the Field on [**********] prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2, this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set

forth above (the "Termination Notice Period") and the terms of Schedule 7 shall apply. Except as set forth in this Section 19.2, Section 19.8 (last paragraph), or Schedule 7, during the Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products in the Field in accordance with Plans. During the Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Company hereunder and in any event upon the expiration of the applicable Termination Notice Period, whether or not any such notice is given by Regeneron, (a) the licenses and rights granted to Company hereunder shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the applicable Termination Notice Period) and (b) Company will promptly take the actions required by Schedule 7 and Regeneron will reasonably cooperate with Company (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory. In addition, during the Termination Notice Period,[**********,] and (ii) neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the non-breaching Party from the Collaboration, taken as a whole.

19.4 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, effective immediately, upon written notice to Company, if Section 20.16 of this Agreement shall have been breached. For the avoidance of doubt, Company will not be deemed to have breached Section 20.16, and Regeneron shall not have the right to terminate this Agreement, as a result of an inadvertent breach of Section 20.16 arising from (a) discussion with any Third Parties that are initiated by such Third Parties, are not publicly disclosed and do not result in any actions referred to in paragraphs (a) through (g) of Section 20.16 or (b) any informal discussions covering general corporate or other business matters the purpose of which is not to effectuate or lead to any of the actions referred to in paragraphs (a) through (g) of Section 20.16.

19.6 [**********].

19.7 Effect of Termination.

(a) Except as set forth in Section 19.7(b) below, upon termination of this Agreement prior to expiration of the Term (and during the applicable Termination Notice Period or 6-Month Notice Period), the provisions of Schedule 7 shall apply, and except to the extent required by Company to fulfill its obligations pursuant to Schedule 7, (i) all licenses and rights granted by Regeneron to Company hereunder shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Company to Regeneron hereunder with respect to Company Products shall automatically terminate, and revert to Company, and (iii) the licenses from Company and its Affiliates

to Regeneron referred to in Schedule 7 shall come into full force and effect. In addition, upon termination of this Agreement prior to expiration of the Term (and during the applicable Termination Notice Period or 6-Month Notice Period), the following paragraphs of Schedule 8 shall apply with respect to any Company Products: (i) paragraph 1 of Schedule 8, (ii) paragraph 3 of Schedule 8 and (iii) paragraph 4 of Schedule 8. If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, then Company shall pay to Regeneron, in addition to any other amount payable by Company to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to (i) fifty percent (50%) of the Development Costs incurred by Regeneron under the Global Development Plan but excluding the Aggregate Regeneron Payment Amount, and (ii) one hundred percent (100%) of the Development Costs incurred by Regeneron under the Territory Development Plan, during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

(b) Upon termination of this Agreement by Company pursuant to Section 19.3 or 19.4, the provisions of Schedule 8 shall apply with respect to any Company Product and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 8, (i) all licenses and rights granted by Company to Regeneron hereunder with respect to Company Products shall automatically terminate, and revert to Company, (ii) all licenses and rights granted by Regeneron to Company hereunder with respect to Regeneron Products shall automatically terminate and revert to Regeneron and (iii) the licenses from Regeneron and its Affiliates to Company referred to in Schedule 8 shall come into full force and effect for the Company Products. In addition, upon termination of this Agreement by Company pursuant to Section 19.3 or 19.4, the following paragraphs of Schedule 7 shall apply with respect to any Regeneron Products: (i) paragraph 1 of Schedule 7, (ii) paragraph 3 of Schedule 7 and (iii) paragraph 4 of Schedule 7.

(c) [**********].

19.8 Survival of Obligations. Except as otherwise provided in this Article 19, Schedule 7 or Schedule 8, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Company nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance Payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero;

(b) subject to the provisions of this Article 19, including Schedule 7 and Schedule 8 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article 16, as well as other provisions (including, without limitation, Sections 6.16, 7.5, 9.7, 9.8, 9.10 and 10.3, and Articles 12 (with respect to Joint Inventions), 16, 17, 19 and 20) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and

(c) such expiration or termination and this Article 19 shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

Notwithstanding the foregoing or any other term or provision of this Agreement, (i) if Company terminates this Agreement under Section 19.2 or Section 19.6 and, during the Termination Notice Period or 6-Month Notice Period, as the case may be, Regeneron enters into a license agreement for a Licensed Product in the Field in the Territory substantially similar in scope as, and providing for the assumption and performance by the counterparty thereto of the obligations of Company under, this Agreement, Company's continuing obligations under the Plans pursuant to Section 19.2 or Section 19.6, as applicable, shall expire, and (ii) upon termination of this Agreement for any reason other than a material breach by Regeneron and consequent termination by Company under Section 19.3, except as set forth in Section 19.7(c), Regeneron's obligations with respect to Global Development Balance Payments to Company provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero.

ARTICLE XX
MISCELLANEOUS

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to conflict of laws principles. Except as set forth in Article 10, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 9 attached hereto and shall be (a) delivered personally,

(b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement contains the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Company and Regeneron.

20.6 Headings. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either

Company or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Company or (b) the prior written consent of Company in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Company Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Without limiting the foregoing, each Party shall take reasonable efforts to ensure that each of its Affiliates engaged in the development or commercialization of ophthalmic products or technologies and which have know-how or technologies that are materially useful for the Development or Commercialization of Licensed Products, engage in the Development or Commercialization of Licensed Products or otherwise license their Know-How under this Agreement. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product or will otherwise license its Know-How under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

20.13 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the

foregoing, Article 17 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Company Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Company nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Company, and Company's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR COMPANY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS .

20.16 Standstill Agreement. During the period commencing on the Effective Date and expiring on the date which is five (5) years after the end of the Term, neither Company nor any of its Affiliates (for purposes of this Section 20.16, Company, together with such Affiliates, being referred to as the "Investor") shall:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock or any securities convertible into or exchangeable for Shares of Then Outstanding Capital Stock, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock, if after giving effect to such acquisition (and assuming the conversion of all convertible securities), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended) twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted

in Investor's ownership totaling twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock;

(b) directly or indirectly, propose or nominate for election to the Board of Directors of Regeneron any Person whose nomination has not been approved by a majority of the Board of Directors of Regeneron, or vote or cause to be voted in favor of such Person for election to the Board of Directors of Regeneron any Shares of Then Outstanding Capital Stock;

(c) directly or indirectly, accept or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of Regeneron (an "Acquisition Proposal");

(d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Securities Exchange Act) in opposition to the recommendation of a majority of the Board of Directors of Regeneron with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Capital Stock of Regeneron or any of its Affiliates;

(e) deposit any Shares of Then Outstanding Capital Stock in a voting trust or subject any Shares of Then Outstanding Capital Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Capital Stock;

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above;

(g) request or propose that Regeneron or any of Regeneron's officers or its Board of Directors amend, waive, or consider the amendment or waiver of any provisions set forth in this Section 20.16; or

(h) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in clauses (a) through (g) above;

provided that the mere voting of any Shares of Then Outstanding Capital Stock held by the Company shall not constitute a violation of any of clauses (a) through (f) above.

20.17 Termination of Standstill. Provided Investor has not violated Section 20.16(d), (f) or (h) with respect to the Offeror referred to in this Section 20.17, the restrictions contained in Section 20.16 shall terminate upon the earlier to occur of (a) the public announcement by an Offeror of an Acquisition Proposal; (b) the acquisition by an Offeror (other than Dr. Leonard Schleifer or his Affiliates) of beneficial ownership of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by the Offeror, represents more than [**********] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock; (c) the issuance by Regeneron to a Third Party

(other than an underwriter in a public offering which promptly distributes such shares to the public) of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by such Third Party, represents more than [**********] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock, if Regeneron does not enter into a standstill agreement with such Third Party for a time period and upon terms substantially similar to the provisions of Section 20.16; (d) a sale of all or substantially all of the assets of Regeneron (other than to a wholly owned subsidiary of Regeneron); or (e) a liquidation or dissolution of Regeneron, which would give rise to a termination of this Agreement pursuant to Section 19.4; provided, however, that if any of the transactions referred to in (a), (b) or (d) above terminates and Regeneron has not made a public announcement of its intent to solicit or engage in a transaction referred to in Section 20.16 (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of Regeneron, then the restrictions contained in Section 20.16 shall again be applicable.

20.18 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.19 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

IN WITNESS WHEREOF, Company and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

BAYER HEALTHCARE LLC

By /s/ Jeffrey M. Greenman
Name: Jeffrey M. Greenman
Title: General Counsel and Secretary

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration and Chief Financial Officer

SCHEDULE 1

Manufacturing Cost

"Manufacturing Cost" as used in this Agreement shall be determined as provided in this Schedule 1.

A. General Principles

1. Regeneron shall supply Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements at Fully Burdened Manufacturing Cost, calculated as described in Section B below.

2. To the extent that a Manufacturing Plan includes the use of Formulated Bulk Product or Finished Product that was Manufactured by Regeneron prior to the Effective Date, Regeneron shall supply such Formulated Bulk Product or Finished Product at its actual average Fully Burdened Manufacturing Cost, calculated as described in Section B below, plus Cost of Finishing, as described in Section C below.

3. [**********]

4. If a Manufacturing Plan calls for Regeneron to reserve its facility to Manufacture Formulated Bulk Product, including, without limitation, purifying/processing the bulk drug substance, and the Parties subsequently amend the Manufacturing Plan such that the facility is not used as originally set forth therein, then Regeneron shall be reimbursed for what otherwise would have been its Fully Burdened Manufacturing Cost as if such facility had been used for Manufacturing as originally required in the Manufacturing Plan, except for such variable costs as are actually avoided or mitigated; provided, however, that Regeneron shall not be reimbursed hereunder if such amendment of the Manufacturing Plan has been agreed upon at least twelve (12) months prior to its effective date.

[**********]

SCHEDULE 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the Territory Profit Split for such Quarter (as set forth in Part I), plus (b) the Regeneron Reimbursement Amount for such Quarter (as set forth in Part II), plus or minus (c) the Global True-Up (as set forth in Part III), minus (d) the Global Development Balance Payment (commencing in the Quarter of the First Commercial Sale in a Major Market Country) (as set forth in Part IV). In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Company to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Company in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. TERRITORY PROFIT SPLIT

The "Territory Profit Split" shall mean fifty percent (50%) of Territory Profits in a Quarter. "Territory Profits" shall mean aggregate Net Sales in the Territory in the Quarter less the sum of aggregate COGS and aggregate Shared Promotion Expenses incurred by both Parties in the Territory in the Quarter.

An example of a calculation of the Territory Profit Split in a Quarter would be:

	Aggregate	Company	Regeneron	Territory Profit Split
Net Sales in the Territory	1000	1000		
COGS	(50)	(50)	0	
Shared Promotion Expenses	(350)	(300)	(50)	
Territory Profits	600			300

II. REGENERON REIMBURSEMENT AMOUNT

The "Regeneron Reimbursement Amount" for a Quarter shall mean (a) Shared Promotion Expenses incurred by Regeneron in the Quarter (if any), plus (b) Commercial Supply Costs incurred by Regeneron in the Quarter (if any), plus (c) Development Costs incurred by Regeneron under the Territory Development Plan in the Quarter (if any).

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Promotion Expenses	50
Regeneron Commercial Supply Costs	10
Regeneron Development Costs under Territory Development Plan	5
Regeneron Reimbursement Amount	65

III. GLOBAL TRUE-UP

The "Global True-Up" for a Quarter shall mean (a) fifty percent (50%) of the sum of (i) aggregate Development Costs incurred by both Parties under the Global Development Plan in the Quarter and (ii) aggregate Other Shared Expenses incurred by both Parties in the Quarter, minus (b) one hundred percent (100%) of the sum of (i) Development Costs incurred by Company under the Global Development Plan in the Quarter and (ii) Other Shared Expenses incurred by Company during the Quarter. If the Global True-Up is a positive number, it shall be added in the calculation of the Quarterly True-Up and, if it is a negative number, the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.

An example of a calculation of the Global True-Up in a Quarter would be:

	Aggregate	Company	Regeneron	Global True-Up
Development Costs under Global Development Plan	80	30	50	
Other Shared Expenses	40	35	5	
Total	120	65	55	(5)

IV. GLOBAL DEVELOPMENT BALANCE PAYMENT

The "Global Development Balance" for a Quarter shall mean (a) twenty-five percent (25%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plan from January 1, 2007 through the close of such Quarter [(**********)] plus (b) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Territory Development Plan from the Effective Date through the close of such Quarter [(**********)] less (c) the aggregate amount of Global Development Balance Payments included in the calculation of the Quarterly True-Up in all prior Quarters.

The "Global Development Balance Payment" shall mean, [**********]

An example of a calculation of the Global Development Balance Payment in a Quarter would be:

Territory Profit Split	300
Global Development Balance	200
[**********]	[****]
Global Development Balance Payment	[***]

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-up in a Quarter would be:

Territory Profit Split	300
Regeneron Reimbursement Amount	65
Global True-Up	(5)
Global Development Balance Payment	[****]
Quarterly True-up	[***]

In this example, Company would pay Regeneron [***] in accordance with the terms set forth in Article 9.

A more detailed illustration of the calculations under this Schedule 2 will be prepared by the JFC promptly after the Effective Date.

SCHEDULE 3

Milestone Payments

I. DEVELOPMENT MILESTONES

The following non-refundable, non-creditable milestone payments shall be payable by Company to Regeneron upon the achievement of each applicable milestone event set forth below for each Regeneron Product in each Major Indication (but in no event more than two (2) Major Indications per Milestone Event). The term "Major Indication" shall include (i) the neovascular form of age-related macular degeneration, (ii) diabetic macular edema, [**********]. If an indication in the Field that is not initially considered by the Parties to be a Major Indication later is determined to be a Major Indication, then within thirty (30) days of such determination, Company shall pay to Regeneron any milestone payments for previous Milestone Events (as set forth below) that occurred with respect to the Development of any Regeneron Product(s) in such indication in the Territory.

Milestone	Payment	Milestone Event
1.	US $20,000,000	For each Regeneron Product, upon administration of the Regeneron Product to the first patient in the first Phase 3 Trial for any Major Indication identified in a Development Plan
2.	[**********]	[**********]
3.	[**********]	[**********]
4.	[**********]	[**********]

For clarity and by way of example only, [**********]

II. SALES MILESTONES

In addition to all other amounts payable under this Agreement, Company shall make the following additional non-refundable, non-creditable milestone payments to Regeneron based on the aggregate Net Sales in any twelve (12) consecutive month time period ("Twelve Month Period"):

Milestone	Payment	Milestone Event
1.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed US $200,000,000
2.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]

Milestone	Payment	Milestone Event
3.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
4.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
5.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
6.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
7.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
8.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
9.	[**********]	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]

For clarity, "aggregate Net Sales" means the total of Net Sales of all Licensed Products in the Field in the Territory. For further clarity, one or more of the milestone payments set forth in this Section II of Schedule 3 may become payable based on the same milestone event. For example, [**********].

For purposes of further clarification, each separate milestone in this Section II of Schedule 3 may be achieved only once and the milestone numbers are included for reference purposes only.

For purposes of this Schedule 3, Net Sales will be converted to United States Dollars using the currency conversion procedure described in Section 9.6.

SCHEDULE 4

Existing Licenses

[**********]

SCHEDULE 5

Initial Development Plan

[**********]

SCHEDULE 6

Regeneron Patent Rights

[**********]

SCHEDULE 7

Termination Arrangements

1. Company shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information of Regeneron and its Affiliates, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any New Information and Party Information of Regeneron and its Affiliates. In addition, at Regeneron's request, Company shall collect and transfer to Regeneron any remaining inventory of Regeneron Product Promotional Materials, Regeneron Product sales training materials, Regeneron Product samples, and Regeneron Product inventory. Notwithstanding the foregoing, Company may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Excluded Territory Intellectual Property existing at the effective date of termination to Develop, Manufacture and Commercialize Regeneron Products in the Field.

3. Company shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Regeneron Products in the Field. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Company shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Company or its Affiliates or any of its Sublicensees to the extent specifically relating to Regeneron Products.

(b) Company shall assign and transfer to Regeneron (or its nominee) Company's entire right, title and interest in and to all Product Trademarks and Promotional Materials relating to Regeneron Products; provided that nothing herein is intended to convey any rights in or to Company's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Company shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Regeneron Products in the Field in the Territory) of all information (including any New Information) in its possession or

under its control to the extent directly relating to any Regeneron Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Company, or such other format as may be reasonably requested by Regeneron.

(d) Company shall use Commercially Reasonable Efforts to assign to Regeneron any applicable sublicenses to the extent related to any Regeneron Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to Development, Manufacture or Commercialization of any Regeneron Product in the Field in the Territory, as reasonably requested by Regeneron and subject to the German Employee Invention Act.

(e) Without limitation of Company's other obligations under this Schedule 7, to the extent Company or its Affiliate is Manufacturing (in whole or in part) Regeneron Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Company (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of Regeneron Products, and Regeneron shall purchase such Regeneron Products, at the same price, and on such other terms and conditions on which Company was supplying, or in the absence of termination would have been required to supply, such Regeneron Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Company that Regeneron is able to Manufacture or have Manufactured Regeneron Products on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture, and Commercialization of the Regeneron Products in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Regeneron shall not be required to provide Company any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 7; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Company may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

SCHEDULE 8

Termination Arrangements

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Company or, at Company's request, destroy, all documents containing New Information or Party Information of Company and its Affiliates, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any New Information related to the Development, Manufacture and Commercialization of Company Products and any Party Information of Company and its Affiliates. In addition, at Company's request, Regeneron shall collect and transfer to Company any remaining inventory of Company Product Promotional Materials, Company Product sales training materials, Company Product samples and Company Product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.

2. Company and its Affiliates shall have a worldwide, fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Regeneron Excluded Territory Intellectual Property existing at the effective date of termination to Develop, Manufacture and Commercialize Company Products in the Field.

3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Company to enable Company (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Company Products in the Field. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Regeneron shall transfer and assign to Company (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to Company Products.

(b) Regeneron shall assign and transfer to Company (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for Company Products and Promotional Materials relating to Company Products; provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.

(c) Regeneron shall provide to Company (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Company Products) of all

information (including any New Information) in its possession or under its control to the extent directly relating to any Company Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Company.

(d) Regeneron shall use Commercially Reasonable Efforts to assign to Company any applicable sublicenses to the extent related to any Company Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to Development, Manufacture or Commercialization of any Company Product in the Field, as reasonably requested by Company, and subject to the German Employee Invention Act.

(e) Without limitation of Regeneron's other obligations under this Schedule 8, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) Company Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Company with Clinical Supply Requirements and/or Commercial Requirements of Company Products, and Company shall purchase such Company Products, at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Company Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Company notifies Regeneron that Company is able to Manufacture or have Manufactured Company Products on comparable financial terms.

4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Company Products in the Field hereunder to Company (or its Sublicensee or Third Party designee) as soon as is reasonably possible.

5. For the avoidance of doubt, Company shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 8; provided, however, that Company shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Company of such licenses or other rights.

SCHEDULE 9

Notices

(a) If to Company:
Bayer HealthCare LLC
511 Benedict Avenue
Tarrytown, New York 10591
U.S.A.

With copy to:

Bayer HealthCare AG
51368 Leverkusen, Germany
Attention: General Counsel

And a copy to:

Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, Connecticut 06516
U.S.A.
Attention: General Counsel

(b) If to Regeneron:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
U.S.A.
Attention: President
Copy: General Counsel

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Nine months ended September 30,
	2001	2002	2003	2004	2005	2006
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	$(75,178)	$(124,350)	$(107,395)	$ 41,565	$(95,456)	$ (72,179)
Fixed charges	3,888	13,685	14,108	14,060	13,687	10,232
Amortization of capitalized interest	—	—	33	78	78	58
Interest capitalized	—	(222)	(276)	—	—	—
Adjusted earnings	$(71,290)	$(110,887)	$ (93,530)	$ 55,703	$(81,691)	$ (61,889)
Fixed charges:						
Interest expense	$ 2,657	$ 11,859	$ 11,932	$ 12,175	$ 12,046	$ 9,033
Interest capitalized	—	222	276	—	—	—
Assumed interest component of rental charges	1,231	1,604	1,900	1,885	1,641	1,199
Total fixed charges	$ 3,888	$ 13,685	$ 14,108	$ 14,060	$ 13,687	$ 10,232
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the nine months ended September 30, 2006, the ratio coverage was less than 1:1. To achieve a coverage ration of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Nine months ended September 30,
	2001	2002	2003	2005	2006
Coverage deficiency	$75,178	$124,572	$107,638	$95,378	$72,121

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2006

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2006

/s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
November 6, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
November 6, 2006

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 5/4/2007

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2007

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☑

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of April 30, 2007:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,270,353
Common Stock, $0.001 par value	63,688,790

REGENERON PHARMACEUTICALS, INC.
Table of Contents
March 31, 2007

	Page Numbers
PART I FINANCIAL INFORMATION	
Item 1 Financial Statements	
Condensed balance sheets (unaudited) at March 31, 2007 and December 31, 2006	3
Condensed statements of operations (unaudited) for the three months ended March 31, 2007 and 2006	4
Condensed statement of stockholders' equity (unaudited) for the three months ended March 31, 2007	5
Condensed statements of cash flows (unaudited) for the three months ended March 31, 2007 and 2006	6
Notes to condensed financial statements (unaudited)	7-12
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	13-27
Item 3 Quantitative & Qualitative Disclosure About Market Risk	27-28
Item 4 Controls and Procedures	28
PART II OTHER INFORMATION	
Item 1 Legal Proceedings	28
Item 1A Risk Factors	28-45
Item 6 Exhibits	45
SIGNATURE PAGE	46
EX-10.1: NON-EXCLUSIVE LICENSE AND MATERIAL TRANSFER AGREEMENT	
EX-12.1: STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO COMBINED FIXED CHARGES	
EX-31.1: CERTIFICATION	
EX-31.2: CERTIFICATION	
EX-32: CERTIFICATION	

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT MARCH 31, 2007 AND DECEMBER 31, 2006 (Unaudited)
(In thousands, except share data)

	March 31, 2007	December 31, 2006
ASSETS		
Current assets		
Cash and cash equivalents	$ 156,484	$ 237,876
Marketable securities	295,910	221,400
Accounts receivable	33,632	7,493
Prepaid expenses and other current assets	3,137	3,215
Total current assets	489,163	469,984
Restricted cash	1,600	1,600
Marketable securities	60,981	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	47,781	49,353
Other assets	1,906	2,170
Total assets	$ 601,431	$ 585,090
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 20,081	$ 21,471
Deferred revenue, current portion	63,523	23,543
Total current liabilities	83,604	45,014
Deferred revenue	121,138	123,452
Notes payable	200,000	200,000
Total liabilities	404,742	368,466
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,270,353 in 2007 and 2006	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 63,395,134 in 2007 and 63,130,962 in 2006	63	63
Additional paid-in capital	914,317	904,407
Accumulated deficit	(717,534)	(687,617)
Accumulated other comprehensive loss	(159)	(231)
Total stockholders' equity	196,689	216,624
Total liabilities and stockholders' equity	$ 601,431	$ 585,090

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended March 31, 2007	2006
Revenues		
Contract research and development	$ 13,645	$ 14,587
Contract manufacturing		3,632
Technology licensing	2,143	
	15,788	18,219
Expenses		
Research and development	41,235	32,084
Contract manufacturing		1,852
General and administrative	8,202	5,946
	49,437	39,882
Loss from operations	(33,649)	(21,663)
Other income (expense)		
Investment income	6,743	3,481
Interest expense	(3,011)	(3,011)
	3,732	470
Net loss before cumulative effect of a change in accounting principle	(29,917)	(21,193)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")		813
Net loss	$ (29,917)	$ (20,380)
Net loss per share amounts, basic and diluted:		
Net loss before cumulative effect of a change in accounting principle	$ (0.46)	$ (0.37)
Cumulative effect of adopting SFAS 123R		0.01
Net loss	$ (0.46)	$ (0.36)
Weighted average shares outstanding, basic and diluted	65,563	56,727

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2007
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
Balance, December 31, 2006	2,270	$ 2	63,131	$ 63	$ 904,407	$ (687,617)	$ (231)	$ 216,624	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			199		1,958			1,958	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367			1,367	
Stock-based compensation expense					6,585			6,585	
Net loss						(29,917)		(29,917)	$ (29,917)
Change in net unrealized loss on marketable securities							72	72	72
Balance, March 31, 2007	2,270	$ 2	63,395	$ 63	$ 914,317	$ (717,534)	$ (159)	$ 196,689	$ (29,845)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Three months ended March 31, 2007	2006
Cash flows from operating activities		
Net loss	$ (29,917)	$ (20,380)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	2,855	3,798
Non-cash compensation expense	6,585	4,079
Cumulative effect of a change in accounting principle		(813)
Changes in assets and liabilities		
(Increase) decrease in accounts receivable	(26,139)	25,511
(Increase) decrease in prepaid expenses and other assets	(440)	1,023
Increase in inventory		(92)
Increase (decrease) in deferred revenue	37,666	(4,779)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	152	(3,069)
Total adjustments	20,679	25,658
Net cash (used in) provided by operating activities	(9,238)	5,278
Cash flows from investing activities		
Purchases of marketable securities	(186,177)	(74,541)
Sales or maturities of marketable securities	113,262	64,317
Capital expenditures	(1,197)	(646)
Net cash used in investing activities	(74,112)	(10,870)
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	1,958	3,416
Net cash provided by financing activities	1,958	3,416
Net decrease in cash and cash equivalents	(81,392)	(2,176)
Cash and cash equivalents at beginning of period	237,876	184,508
Cash and cash equivalents at end of period	$ 156,484	$ 182,332

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2006 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three months ended March 31, 2007 and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March 31,	
	2007	2006
Net loss (Numerator)	$(29,917)	$(20,380)
Weighted-average shares, in thousands (Denominator)	65,563	56,727
Basic and diluted net loss per share	$ (0.46)	$ (0.36)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2007 and 2006 diluted per share amounts because their effect would have been antidilutive, include the following:

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended March 31,	
	2007	2006
Stock Options:		
Weighted average number, in thousands	15,549	14,401
Weighted average exercise price	$ 15.65	$ 14.27
Restricted Stock:		
Weighted average number, in thousands		54
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2007 and December 31, 2006 are $580 and $755, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2006 and December 31, 2005 are $233 and $234, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2006 and 2005 are $1,367 and $1,884, respectively, of accrued Company 401 (k) Savings Plan contribution expense. In the first quarter of 2007 and 2006, the Company contributed 64,532 and 120,960 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2007 and December 31, 2006 are $2,054 and $1,532, respectively, of accrued interest income. Included in marketable securities at March 31, 2006 and December 31, 2005 are $656 and $1,228, respectively, of accrued interest income.

4. Accounts Receivable

Accounts receivable as of March 31, 2007 and December 31, 2006 consist of the following:

	March 31, 2007	December 31, 2006
Receivable from the sanofi-aventis Group	$ 9,676	$ 6,900
Receivable from Bayer HealthCare LLC	3,070	
Receivable from Astellas Pharma Inc.	20,000	
Other	886	593
	$ 33,632	$ 7,493

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2007 and December 31, 2006 consist of the following:

	March 31, 2007	December 31, 2006
Accounts payable	$ 4,805	$ 4,349
Accrued payroll and related costs	5,332	9,932
Accrued clinical trial expense	2,673	2,606
Accrued expenses, other	2,229	2,292
Interest payable on convertible notes	5,042	2,292
	$ 20,081	$ 21,471

6. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended March 31, 2007 and 2006, the components of comprehensive loss are:

	Three months ended March 31,	
	2007	2006
Net loss	$(29,917)	$(20,380)
Change in net unrealized gain (loss) on marketable securities	72	99
Total comprehensive loss	$(29,845)	$(20,281)

7. License Agreements

AstraZeneca

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that will allow AstraZeneca to utilize the Company's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable up-front payment to the Company which was deferred and is being recognized as revenue ratably over approximately the first year of the agreement. AstraZeneca also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's VelocImmune technology. In the first quarter of 2007, the Company recognized $2,143 of revenue in connection with the AstraZeneca license agreement. At March 31, 2007, deferred revenue was $17,857.

Astellas

On March 30, 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that will allow Astellas to utilize the Company's VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable up-front payment to the Company, which was received in April 2007. Astellas also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. At March 31, 2007, the $20.0 million up-front payment from Astellas was included in accounts receivable and deferred revenue.

8. Income Taxes

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has no unrecognized tax benefits.

The Company is primarily subject to U.S. federal and New York State income tax. Tax years subsequent to 1991 remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and March 31, 2007, the Company had no accruals for interest or penalties related to income tax matters.

9. Segment Information

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing. Due to the expiration of the Company's manufacturing agreement with Merck & Co., Inc. in October 2006, beginning in 2007, the Company only has a research and development business segment.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to activities conducted under contract research and technology licensing agreements.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006, the Company produced a vaccine intermediate for Merck under the Merck Agreement, which expired in October 2006.

The table below presents information about reported segments for the three months ended March 31, 2007 and 2006.

	Three months ended March 31, 2007		
	Research & Development	Reconciling Items	Total
Revenues	$ 15,788	—	$ 15,788
Depreciation and amortization	2,594	261	2,855
Non-cash compensation expense	6,585	—	6,585
Interest expense	—	3,011	3,011
Net (loss) income	(33,649)	3,732 (1)	(29,917)
Capital expenditures	1,022	—	1,022
Total assets	81,413	520,018 (2)	601,431

	Three months ended March 31, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 14,587	$3,632	—	$ 18,219
Depreciation and amortization	3,537	— (3)	$ 261	3,798
Non-cash compensation expense	3,984	95	(813)(4)	3,266
Interest expense	—	—	3,011	3,011
Net (loss) income	(23,443)	1,780	1,283 (1)	(20,380)
Capital expenditures	645	—	—	645
Total assets	67,159	4,526	330,404 (2)	402,089

(1) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the three months ended March 31, 2006, also includes the cumulative effect of adopting Statement of Financial Accounting Standards No. ("SFAS") 123R, *Share-Based Payment*.

(2) Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

(3) Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

(4) Represents the cumulative effect of adopting SFAS 123R.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

10. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

11. Future Impact of Recently Issued Accounting Standards

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 159 on the Company's financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: IL-1 Trap (rilonacept) in various inflammatory indications, the VEGF Trap in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. In October 2006, we entered into a collaboration with Bayer HealthCare LLC for the development of the VEGF Trap-Eye. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the VelocImmune platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move our first new antibody product candidate into clinical trials in the fourth quarter of 2007. We plan to introduce two new antibody product candidates into clinical development each year. We continue to invest in the

development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of March 31, 2007:

1. IL-1 Trap — Inflammatory Diseases

The IL-1 Trap (rilonacept) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

We recently completed the 24-week open-label safety extension phase of the Phase 3 clinical program in CAPS and are completing the trial analysis. We are preparing to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the second quarter of 2007. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

In October 2006, we announced positive data from this Phase 3 trial, which was designed to provide two separate demonstrations of efficacy for the IL-1 Trap within a single group of adult patients suffering from CAPS. This Phase 3 trial included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: $p < 0.0001$ and Part B: $p < 0.001$). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive the IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ($p<0.0001$). Following a 9-week interval during which all patients received the IL-1 Trap, a "randomized withdrawal" study (Part B) was performed, in which the patients in Part A were re-randomized to either switch to placebo or continue treatment with the IL-1 Trap in a double-blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on the IL-1 Trap who had no significant change ($p<0.001$). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on the IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study.

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of the IL-1 Trap in other indications in which IL-1 may play a role. Based on preclinical evidence that IL-1 appears to play a critical role in gout, we initiated a proof of concept study of the IL-1 Trap in gout in the first quarter of 2007. We are also preparing to initiate exploratory proof of concept studies of the IL-1 Trap in other indications.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

2. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis. Currently, the collaboration is conducting Phase 2 studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the FDA granted Fast Track designation to the VEGF Trap for the treatment of SMA. Sanofi-aventis reported in February

2007 that a registration filing is possible for the VEGF Trap in at least one of these single-agent indications in 2008.

In addition, six new Phase 2 single-agent studies have begun in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in relapsed/refractory multiple myeloma, metastatic colorectal cancer, recurrent or metastatic cancer of the urothelium, locally advanced or metastatic gynecological soft tissue sarcoma, recurrent malignant gliomas, and metastatic breast cancer. We and sanofi-aventis are working to finalize plans with NCI/CTEP for at least four additional trials in different cancer types.

We and sanofi-aventis intend to initiate five Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, the first three of which are planned to begin in 2007. The companies plan to initiate these Phase 3 trials in the following indications:

- first-line metastatic hormone resistant prostate cancer in combination with Taxotere® (Aventis),
- first-line metastatic pancreatic cancer in combination with gemcitabine-based regimen,
- first-line gastric cancer in combination with Taxotere® (Aventis),
- second-line non-small cell lung cancer in combination with Taxotere® (Aventis), and
- second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan).

Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the planned Phase 3 clinical program. The companies have previously summarized information from two of these safety and tolerability trials. One study is evaluating the VEGF Trap in combination with oxaliplatin, 5-flourouracil, and leucovorin (FOLFOX4) in a Phase 1 trial of patients with advanced solid tumors. Another study is evaluating the VEGF Trap in combination with irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a Phase 1 trial of patients with advanced solid tumors. Abstracts published in the 2006 ASCO Annual Meeting Proceedings reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The companies are also evaluating the VEGF Trap in separate Phase 1b studies in combination with Taxotere® (Aventis), cisplatin, and 5-fluorouracil; with Taxotere® (Aventis) and cisplatin; and with gemcitabine-erlotinib.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting

angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (Genentech) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to $400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In the second quarter of 2006, we initiated a 150 patient, 12 week, Phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. In March 2007, we announced positive preliminary data from a pre-planned interim analysis of this study. The VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns, $p < 0.0001$). Mean change from baseline in visual acuity, a key secondary endpoint of

the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters, $p < 0.0001$). Moreover, patients in the dose groups that received only a single dose, on average, compared to baseline, demonstrated a decrease in excess retinal thickness ($p < 0.0001$) and an increase in visual acuity ($p = 0.012$) at 12 weeks. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. Detailed data from this interim analysis is scheduled for presentation at an upcoming scientific conference. We also expect to complete three-month data on all 150 patients enrolled in the study by the end of 2007. We are also conducting a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in wet AMD. An initial Phase 3 trial of the VEGF Trap-Eye in wet AMD utilizing the new formulation is planned to begin in the third quarter of 2007, and a second Phase 3 trial is planned once the full data from the Phase 2 trial has been analyzed.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with DME. We expect to initiate a Phase 2 trial in DME in the second half of 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare and can earn up to $110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market

countries outside the United States. We can also earn up to $135.0 million in sales milestones if total annual sales of the VEGF Trap outside the United States achieve certain specified levels starting at $200.0 million.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2007, we had a cumulative loss of $717.5 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs utilizing our new technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2007 and plans over the next 12 months are as follows:

Clinical Program	2007 Events to Date	2007-8 Plans
VEGF Trap – Oncology	• NCI/CTEP initiated six Phase 2 studies of the VEGF Trap as a single agent	• Sanofi-aventis to initiate at least three of five Phase 3 studies of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer indications • NCI/CTEP to initiate at least four new exploratory efficacy/safety studies
VEGF Trap-Eye (intravitreal injection)	• Reported positive interim results of Phase 2 trial in wet AMD	• Initiate first Phase 3 trial in wet AMD of the VEGF Trap-Eye compared with Lucentis® (Genentech) • Report final results of Phase 2 trial in wet AMD • Initiate second Phase 3 trial in wet AMD • Report results of the Phase 1 trial in DME • Initiate Phase 2 trial in DME • Explore additional eye disease indications
IL-1 Trap (rilonacept)	• Completed the 24 week open-label safety extension phase of the Phase 3 trial in CAPS	• Submit BLA to the FDA for CAPS • Initiate proof-of-concept studies evaluating the IL-1 Trap in gout and report initial data • Evaluate the IL-1 Trap in other disease indications in which IL-1 may play an important role
VelocImmune		• Initiate first trial for antibody product candidate

License Agreements

AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that will allow AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable up-front payment to us. AstraZeneca also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune technology.

Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that will allow Astellas to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable up-front payment to us, which was received in April 2007. Astellas also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune technology.

Results of Operations

Three Months Ended March 31, 2007 and 2006

Net Income (Loss):

Regeneron reported a net loss of $29.9 million, or $0.46 per share (basic and diluted), for the first quarter of 2007 compared to a net loss of $20.4 million, or $0.36 per share (basic and diluted), for the first quarter of 2006.

Revenues:

Revenues for the three months ended March 31, 2007 and 2006 consist of the following:

(In millions)	2007	2006	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 11.8	$ 13.9	$ (2.1)
Other	1.9	0.7	1.2
Total contract research & development revenue	13.7	14.6	(0.9)
Contract manufacturing revenue		3.6	(3.6)
Technology licensing revenue	2.1		2.1
Total revenue	$ 15.8	$ 18.2	$ (2.4)

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue *(In millions)*	Three months ended March 31, 2007	2006
Regeneron expense reimbursement	$ 9.6	$ 10.8
Recognition of deferred revenue related to up-front payments	2.2	3.1
Total	$ 11.8	$ 13.9

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the first quarter of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the first quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of March 31, 2007, $67.7 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

As described above, in October 2006 we entered into a VEGF Trap-Eye collaboration with Bayer HealthCare. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first $50.0 million will be shared equally; Regeneron is solely responsible for the next $40.0 million; over $90.0 million will be shared equally. Bayer HealthCare reimbursements of shared development expenses incurred by us are recorded as deferred revenue. We will recognize revenue from Bayer HealthCare, in connection with the companies' collaboration, in accordance with SAB 104 and EITF 00-21. When we and Bayer HealthCare have formalized our projected global development plans for the VEGF Trap-Eye, as well as the projected responsibilities of each of the companies under those development plans, we will begin recognizing contract research and development revenue related to payments from Bayer HealthCare. As a result, no contract research and development revenue has been earned from Bayer HealthCare through March 31, 2007 even though Bayer HealthCare will reimburse us for $3.1 million of first quarter 2007 shared VEGF Trap-Eye expenses. As of March 31, 2007, deferred revenue from Bayer HealthCare, which will be recognized in future periods, totaled $78.1 million, consisting of the $75.0 million up-front payment received in October 2006 and reimbursement of $3.1 million of shared VEGF Trap-Eye expenses related to the first quarter of 2007.

Other contract research and development revenue includes $0.7 million recognized in connection with our five-year grant from the National Institutes of Health (NIH).

Contract manufacturing revenue for the first three months of 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the first three months of 2006 was $0.4 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca which allows AstraZeneca to utilize Regeneron's VelocImmune technology in its internal research

programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable up-front payment to us which was deferred and will be recognized as revenue ratably over approximately the first year of the agreement. In the first quarter of 2007, we recognized $2.1 million of technology licensing revenue related to the AstraZeneca agreement.

Expenses:

Total operating expenses increased to $49.4 million in the first quarter of 2007 from $39.9 million in the same period of 2006. Operating expenses in the first quarter of 2007 and 2006 include a total of $6.6 million and $3.9 million, respectively, of non-cash compensation expense related to employee stock option awards (Stock Option Expense), as detailed below:

(In millions)	**For the three months ended March 31, 2007**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 37.4	$ 3.8	$ 41.2
General and administrative	5.4	2.8	8.2
Total operating expenses	$ 42.8	$ 6.6	$ 49.4

(In millions)	**For the three months ended March 31, 2006**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 30.1	$ 2.0	$ 32.1
Contract manufacturing	1.8	0.1	1.9
General and administrative	4.1	1.8	5.9
Total operating expenses	$ 36.0	$ 3.9	$ 39.9

The increase in total Stock Option Expense in the first quarter of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to $41.2 million in the first quarter of 2007 from $32.1 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2007 and 2006:

(In millions)	**Three months ended March 31,**		
Research and development expenses	**2007**	**2006**	**Increase (Decrease)**
Payroll and benefits (1)	$ 13.7	$ 10.0	$ 3.7
Clinical trial expenses	5.3	3.4	1.9
Clinical manufacturing costs (2)	10.5	9.3	1.2
Research and preclinical development costs	6.0	3.5	2.5
Occupancy and other operating costs	5.7	5.9	(0.2)
Total research and development	$ 41.2	$ 32.1	$ 9.1

(1) Includes $3.1 million and $1.6 million of Stock Option Expense for the three months ended March 31, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million and $0.4 million of Stock Option Expense for the three months ended March 31, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to annual salary increases effective January 1, 2007. Clinical trial expenses increased due to higher VEGF Trap-Eye costs primarily related to our Phase 1 and 2 studies in wet AMD and higher IL-1 Trap costs. Clinical manufacturing costs increased due to higher costs related to manufacturing preclinical and clinical supplies of our first antibody drug candidate, which were partly offset by lower costs related to manufacturing VEGF Trap clinical supplies. Research and preclinical development costs increased primarily due to higher preclinical development costs related to our VEGF Trap and human monoclonal antibody programs.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased in the first quarter of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to $8.2 million in the first quarter of 2007 from $5.9 million in the same period of 2006 primarily due to higher Stock Option Expense, as described above, higher compensation expense due, in part, to annual salary increases effective January 1, 2007, higher recruitment and related costs associated with expanding our headcount in 2007, and marketing research and related expenses incurred in 2007 in connection with our IL-1 Trap and VEGF Trap programs.

Other Income and Expense:

Investment income increased to $6.7 million in the first quarter of 2007 from $3.5 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was $3.0 million in the first quarter of 2007 and 2006. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and

present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

Three Months Ended March 31, 2007 and 2006

At March 31, 2007, we had $515.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with $522.9 million at December 31, 2006. In February 2007, we received a $20.0 million non-refundable up-front payment in connection with our new non-exclusive license agreement with AstraZeneca.

Cash (Used in) Provided by Operations:

Net cash used in operations was $9.2 million in the first quarter of 2007, compared to net cash provided by operations of $5.3 million in the first quarter of 2006. Our net losses of $29.9 million in the first quarter of 2007 and $20.4 million in the first quarter of 2006 included $6.6 million and $4.1 million, respectively, of non-cash stock-based employee compensation costs, of which $6.6 million and $3.9 million, respectively, represented Stock Option Expense and, in the first quarter of 2006, $0.2 million represented non-cash compensation expense from Restricted Stock awards. At March 31, 2007, accounts receivable balances increased by $26.1 million, compared to end-of-year 2006, primarily due to a $20.0 million non-refundable up-front payment which was receivable from Astellas in connection with our new non-exclusive license agreement (see "License Agreements" above). Also, our deferred revenue balances at March 31, 2007 increased by $37.7 million, compared to end-of-year 2006, primarily due to the $20.0 million up-front payments received or receivable from AstraZeneca and Astellas, as described above. These payments will be recognized as revenue ratably over approximately the first year of the respective agreements. At March 31, 2006, accounts receivable balances decreased by $25.5 million, compared to end-of-year 2005, primarily due to the January 2006 receipt of a $25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our collaboration agreement to include Japan. Also, our deferred revenue balances at March 31, 2006 decreased by $4.8 million, compared to end-of-year 2005, due primarily to first quarter 2006 revenue recognition of $3.1 million of deferred revenue related to up-front payments from sanofi-aventis. The majority of our cash expenditures in both the first quarter of 2007 and 2006 were to fund research and development, primarily related to our clinical programs.

Cash Used in Investing Activities:

Net cash used in investing activities was $74.1 million in the first quarter of 2007 compared to $10.9 million in the same period of 2006, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first quarter of 2007, purchases of marketable securities exceeded sales or maturities by $72.9 million, whereas in the first quarter of 2006, purchases of marketable securities exceeded sales or maturities by $10.2 million.

Cash Provided by Financing Activities:

Cash provided by financing activities decreased to $2.0 million in the first quarter of 2007 from $3.4 million in the same period in 2006 due to a decrease in issuances of Common Stock in connection with exercises of employee stock options.

License Agreements with AstraZeneca and Astellas:

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a $20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas also will each make up to five additional annual payments of $20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $1.0 million and $0.6 million for the first three months of 2007 and 2006, respectively. During the remainder of 2007, we expect to incur approximately $15 million in capital expenditures primarily to support our manufacturing, development, and research activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2007 will be directed toward the preclinical and clinical development of product candidates, including the IL-1 Trap, VEGF Trap, VEGF Trap-Eye and monoclonal antibodies; approximately 10%-15% of our expenditures for 2007 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2007 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the $200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. Other than the $1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the three months ended March 31, 2007, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2006.

Future Impact of Recently Issued Accounting Standards

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. (SFAS) 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 159 on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure

to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a $1.8 million and $0.9 million change in the fair market value of our investment portfolio at March 31, 2007 and 2006, respectively. The increase in the impact of an interest rate change at March 31, 2007, compared to March 31, 2006, is due primarily to increases in our investment portfolio's balance and duration to maturity at the end of March 2007 versus the end of March 2006.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2006 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2007, we had a cumulative loss of $717.5 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Until the expiration in October 2006 of our agreement with Merck, we received contract manufacturing revenue pursuant to that agreement. The expiration of that agreement has resulted in a significant loss of revenue to Regeneron.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the $200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay

principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too

high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a Phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the Phase 3 clinical program for the IL-1 Trap in CAPS (Cryopyrin Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of the IL-1 Trap.

The efficacy and safety data from the Phase 3 clinical program for the IL-1 Trap in CAPS may be inadequate to support approval for its commercialization in this indication. Moreover, if the safety data from the ongoing clinical trials testing the IL-1 Trap are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for the IL-1 Trap or we may be forced to delay the filing. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for the IL-1 Trap, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize the IL-1 Trap profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the IL-1 Trap in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test the IL-1 Trap in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, the IL-1 Trap may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking the IL-1 Trap. One subject with adult Still's diseases in a study of the IL-1 Trap developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymayalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of the IL-1 Trap in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions or infusion reactions. These

or other complications or side effects could impede or result in us abandoning the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex

legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our VelocImmune technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or

commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2006, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our

collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or

lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis®

(Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Biotechnology Ltd.), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS*1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We intend to file an application with the FDA seeking approval to market the IL-1 Trap for

the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize the IL-1 Trap. Physicians may not prescribe the IL-1 Trap and CAPS patients may not be able to afford the IL-1 Trap if third party payers do not agree to reimburse the cost of IL-1 Trap therapy and this would adversely affect our ability to commercialize the IL-1 Trap profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including the IL-1 Trap, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may

not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 12, 2007, our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. As of April 12, 2007, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 4.4% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 12, 2007, holders of Class A Stock held 26.4% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 12, 2007:

- our current executive officers and directors beneficially owned 13.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007, and 30.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007; and
- our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. In addition, these seven shareholders held 51.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 12, 2007.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
10.1*	— Non-Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
12.1	— Statement re: computation of ratio of earnings to combined fixed charges.
31.1	— Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	— Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: May 4, 2007

By: /s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

NON-EXCLUSIVE LICENSE AND MATERIAL TRANSFER AGREEMENT

This Non-Exclusive License and Material Transfer Agreement ("Agreement") is entered into with an effective date as of March 30, 2007 (the "Effective Date"), by and between Astellas Pharma Inc., a Japanese company with a principal place of business located at 2-3-11 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan ("Company"), and Regeneron Pharmaceuticals, Inc. ("Regeneron"), a New York corporation, with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707.

WITNESSETH

WHEREAS, Regeneron has developed antibody technology, including genetically modified mice and related know-how, useful to generate human monoclonal antibodies;

WHEREAS, Regeneron owns certain patents and patent applications covering its human antibody technology;

WHEREAS, Company desires to obtain certain non-exclusive licenses under Regeneron Technology (as defined below), including the right to commercialize Antibodies (as defined below) generated from the Mice (as defined below), on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, Company and Regeneron agree as follows:

ARTICLE I
DEFINITIONS

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

1.1 "Adjusted Annual Fee" shall mean twenty million United States dollars (US$20,000,000) adjusted in accordance with the US CPI to reflect any increase in the US CPI from the month and year of the Transfer Date until the month and year of the most recently reported US CPI available on the fourth anniversary of the Transfer Date.

1.2 "Affiliate" shall mean, with respect to a Person, any Person that controls, is controlled by, or is under common control with such Person. For purposes of this Section 1.2, "control" shall refer to (a) in the case of a Person that is a corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of a majority of the directors of such Person or (b) in the case of a Person that is an entity, whether or not he, she or it is a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

1.3 "Antibody" shall mean any antibody, or any derivative, or fragment thereof, including any fusions comprising any such antibody, derivative or fragment, that has been Derived from Mice and/or Mice Materials pursuant to this Agreement and any composition or formulation that incorporates or includes any such antibody, derivative, fragment or fusion molecule.

1.4 "Antibody Materials" shall mean **********.

1.5 "Applicable Law" shall mean all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any court, tribunal, arbitrator, agency, commission, official or other instrumentality of (a) any government of any country, (b) a federal, state, province, county, city or other political subdivision thereof or (c) any supranational body.

1.6 "Approved Third Party" shall mean a Third Party approved by Regeneron pursuant to Section 3.6.

1.7 "Breeding Pair" shall mean one (1) male Mouse and one (1) female Mouse.

1.8 "Company Know How" shall have the meaning set forth in Section 7.1(c).

1.9 "Company Patent Rights" shall mean all Patent Rights owned or Controlled by Company and/or its Affiliates, in each case, which claim any composition (or portion thereof) or use of the Antibody, Antibody Materials, Subject Products or Company Know-How.

1.10 "Company Technology" shall mean Company Patent Rights and Company Know-How.

1.11 "Control" and cognates thereof shall mean the ability by a Person to grant (whether directly or through its Affiliates) the right to access or use, or to grant a licence or a sublicense to, or the right to disclose or transfer Regeneron Technology (including, without limitation, Mice), Company Technology or other intellectual property right, or Confidential Information, as the case may be, without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party.

1.12 "Derived" and cognates thereof shall mean obtained, developed, acquired, made, invented, discovered, created, synthesized, designed, or otherwise generated or resulting from. For the avoidance of doubt, an antibody or antibody material shall not be deemed Derived from Mice if Company only uses Company Know-How (other than DNA or amino acid sequence information) to derive antibodies from sources other than Mice or Mice Materials.

1.13 "Diagnostic Subject Product" shall mean each Subject Product approved and sold or offered for sale for diagnostic use.

1.14 "Distributor" shall mean a Third Party appointed to distribute, market and sell the Subject Products in a country or region other than the United States, Canada, France, Germany, Italy, Japan, Spain, or the United Kingdom, even if that Third Party is supplied Subject Products in unpackaged bulk form; provided that such Third Party does not make any royalty or other payment to Company or any of its Affiliates or Licensees with respect to the Subject Product or intellectual property rights outside of the amounts included in the calculation of Net Sales (other than a reasonable and customary up-front payment that is comparable to payments made by Company to a Distributor for the distribution of its other products in the applicable country or region).

1.15 "Exploit" means to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, manufacture, have manufactured, hold/keep (whether for disposal or otherwise), formulate, optimise, have used, export, transport, distribute, promote, market or have sold or otherwise dispose or offer to dispose of a product or process and "Exploitation" shall be construed accordingly.

1.16 "Launch" shall mean the first commercial sale of any Subject Product by Company or its Affiliate or Licensee to a Third Party in a given country.

1.17 "Licensee" shall mean any Third Party that licenses, either directly or through a sublicense, a Subject Product from Company or any of its Affiliates. For the avoidance of doubt, the term "Licensee" shall include any Third Party that licenses a Subject Product from a Licensee but shall not include a Distributor.

1.18 "Mice" shall mean (a) Regeneron's proprietary, genetically modified mice that are described in Exhibit A ********** **********.

1.19 "Mice Inventions" shall have the meaning set forth in Section 2.4.

1.20 "Mice Materials" shall mean **********, but excluding Antibodies and Antibody Materials.

1.21 "Net Sales" shall mean the gross amounts invoiced by Company, Company's Affiliates and/or Licensees on sales of Subject Products, less the following items:

(a) trade, cash and quantity discounts actually allowed and taken directly with respect to such sales;

(b) tariffs, duties, excises and sales taxes imposed upon and paid directly with respect to such sales (reduced by any refunds of such taxes deducted in the calculation of Net Sales for prior periods and, for the avoidance of doubt, no deduction shall be permitted for income or similar taxes);

(c) amounts repaid or credited by reason of rejections, defects, recalls or returns or because of chargebacks, trial prescriptions or rebates;

(d) invoiced amounts that are written off as uncollectible in accordance with Company's accounting policies, as consistently applied over all products of Company, Company's Affiliates and/or Licensees (reduced by any collections of such amounts deducted in the calculation of Net Sales for prior periods); and

(e) as an allowance for transportation costs, distribution expenses, special packaging and related insurance charges, ******* **********.

The deductions set forth in clauses (a), (b), (c), (d) and (e) above shall be determined in accordance with generally accepted accounting principles, as consistently applied by Company across all of its

products. The amounts set forth in clause (b) above shall only be deducted from gross invoiced sales to the extent included in gross invoiced sales.

Transfers of Subject Products among Company and Company's Affiliates and Licensees for the purpose of subsequent resale to Third Parties shall not be counted for purposes of calculating Net Sales; with respect to such transfers, the gross amounts invoiced in connection with the subsequent resale of such Subject Products by Company or its Affiliates or Licensees to Third Parties shall be included in the calculation of Net Sales.

For purposes of determining Net Sales, the Subject Product(s) shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions made without financial consideration for charitable, promotional, preclinical, clinical, regulatory or governmental purposes.

As used in this paragraph, "Combination Products" means Subject Products that contain an Antibody as an active ingredient together with one or more other active ingredients. With respect to Combination Products, the Net Sales used for the calculation of the royalties under Section 4.2 will be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A / (A+B), where A is the standard sales price of the Subject Product, containing the same amount of Antibody as its sole active ingredient as does the Combination Product in question, in the given country, and B is the standard sales price of the ready-for-sale form of a product containing, as its sole active ingredient(s) the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the given country. If, on a country-by-country basis, the therapeutically active ingredient(s) in the Combination Product other than the Subject Product are not sold separately in that country, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A / C, where C is the standard sales price of the Combination Product in such country. If, on a country-by-country basis, neither the Subject Product nor the other active ingredient(s) of the Combination Product is sold separately in said country, Net Sales shall be determined between the Parties in good faith.

1.22 "Party" shall mean Regeneron or Company; "Parties" shall mean Regeneron and Company.

1.23 "Patent Rights" shall mean all patents and patent applications (including provisional patent applications and any continuations of any such patent applications, claims in continuations-in-part to the extent such claims are entirely supported by the specifications of any such patent applications, and any divisionals, provisionals or substitute applications with respect to any such patent applications), any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental patent certificate) of any such patent, and any confirmation patent, registration patent, patent of addition, or inventor's certificate based on or directed to the same invention as any such patent, and all patents and patent applications anywhere in the world that at any time, directly or indirectly, claim priority from, support a claim of priority of or contain substantially identical disclosure as any of the foregoing.

1.24 "Person" shall mean any natural person or any corporation, company, partnership, limited liability company, joint venture, firm or other entity, including without limitation a Party.

1.25 "Progeny" shall mean any mice that are produced or developed by breeding or otherwise reproducing Mice.

1.26 "Regeneron Know-How" shall mean the trade secrets, unpatented technical information, specifications, protocols, and procedures described or referred to in Exhibit A and any unpatented Mice Inventions.

1.27 "Regeneron Patent Rights" shall mean all Patent Rights owned or Controlled by Regeneron and/or its Affiliates as at the Effective Date and, subject to Section 2.5, during the term of this Agreement, in each case, which claim the Mice, Mice Materials or Mice Inventions or the use of the Mice, Mice Materials or Mice Inventions to make Antibodies in general, including, without limitation, the Patent Rights that are listed in Exhibit B. For the avoidance of doubt, Regeneron Patent Rights shall not include (i) any Patent Rights claiming methods relating to Antibody or Antibody Material generation that are not directly related to the Mice or Mice Materials and (ii) any Patent Rights claiming the use of Mice or Mice Materials to make Antibodies against any specific target.

1.28 "Regeneron Technology" shall mean the Regeneron Know-How and Regeneron Patent Rights including with respect to any Mice Invention.

1.29 "Royalty Term" shall have the meaning set forth in Section 4.3.

1.30 "SEC" shall mean the United States Securities and Exchange Commission.

1.31 "Site" shall mean ********** and any site of a Company's Affiliate or Approved Third Party upon prior written notification of the address of such facility(ies) to Regeneron.

1.32 "Subject Product" shall mean any product (including, without limitation, any therapeutic or diagnostic for human or veterinary use) that contains as an ingredient or component an Antibody or Antibody Materials.

1.33 "Therapeutic Subject Products" shall mean all Subject Products except for Diagnostic Subject Products.

1.34 "Third Party" shall mean any Person other than Regeneron, Company, or their respective Affiliates.

1.35 "Transfer Date" shall mean the date upon which the first delivery of Mice from Regeneron are received by Company pursuant to Section 3.3 or **********.

1.36 "US CPI" shall mean the Consumer Price Index —Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index) or such other index as may be mutually agreed upon by the Parties.

1.37 "Valid Claim" shall mean a claim which satisfies both of the conditions set forth in (i) and (ii) below: (i) the relevant claim is either (a) a claim of an issued and unexpired patent

which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through re-issue or disclaimer or otherwise or (b) a claim of a pending patent application which claim was filed in good faith and which has not been pending for more than seven (7) years and that has not been abandoned or finally rejected without the possibility of appeal or refilling, and (ii) the relevant claim would be infringed by a Third Party if such Third Party Exploits a Subject Product.

ARTICLE II
LICENSE

2.1 License Grant. Subject to the terms of this Agreement, Regeneron on behalf of itself and its Affiliates hereby grants to Company a non-exclusive, worldwide license under the Regeneron Technology:

(a) to make Mice at the Site (but not to have Mice made other than by an Approved Third Party) (i) solely by means of breeding Mice with other Mice in accordance with the breeding practices outlined on Exhibit A as supplemented by disclosures made by Regeneron pursuant to Section 3.1 and Section 3.2 and (ii) as specifically set forth in the last sentence of Section 5.4;

(b) to use Mice at the Site (but not to have Mice used other than by an Approved Third Party) supplied by Regeneron or made by or for Company in accordance with (a) above to Derive Mice Materials for the purpose of making or having made Antibodies and/or Antibody Materials for internal research purposes, including for use in human clinical trials; and

(c) to use Mice Materials at the Site (but not to have Mice Materials used other than by an Approved Third Party) to Derive Antibodies and Antibody Materials.

As of the Effective Date, Regeneron has no Affiliates that Control any Regeneron Technology.

2.2 No Sublicense. Company shall not sublicense or otherwise transfer its rights (except as specifically provided in Sections 3.6 and 10.1) granted under Regeneron Technology; provided, however, that Company shall have the right to grant sublicenses under the licenses granted pursuant to Section 2.1 to its Affiliates; provided, further, that Company shall ensure that the terms of each such sublicense are consistent with the terms of this Agreement and that its Affiliates shall not commit any act (including any act of omission) which Company is prohibited from committing directly.

2.3 No Implied Licenses. The grant of the license to Company under Regeneron Technology set forth herein shall not constitute a grant of a license to Company under any Patent Rights or know-how other than the Regeneron Technology.

2.4 Mice Inventions. Company acknowledges and agrees that (a) the licenses granted to it pursuant to Section 2.1 permit Company (and Affiliates and Approved Third Parties) to use the Mice and Mice Materials solely for the purposes set forth therein, (b) neither Company nor any

of its Affiliates shall use the Mice or Mice Materials other than for the purposes set forth in Section 2.1, (c) Company has no right to use and shall not use the Mice or Mice Materials to discover, develop or otherwise make improvements that directly relate to the Mice or Mice Materials ("Mice Inventions") under such grants except for inventions made in the ordinary course of using the Mice and Mice Materials for the purpose of making (or having made) and using Antibodies and Antibody Materials under the grants in Sections 2.1(a) through (c). For the avoidance of doubt, Regeneron acknowledges that Mice Inventions shall not include Antibodies or Antibody Materials and general methods relating to the generation of antibodies or antibody materials. Without limiting any of Regeneron's rights under this Agreement or otherwise, should Company make any Mice Inventions, Company shall promptly disclose to Regeneron, in writing, any such Mice Inventions and shall, and hereby does, assign, for itself and on behalf of its Affiliates, to Regeneron all right, title, and interest it or they have in Mice Inventions without additional compensation. Company agrees, for itself and on behalf of its Affiliates, to execute any and all further instruments, forms of assignments and other documents, and to take such further actions as Regeneron may request, in order to transfer all of Company's (and/or its Affiliates) rights in the Mice Inventions. Without limiting the foregoing, Regeneron shall have the right to prepare, file and prosecute, in Regeneron's name as assignee, patent applications on all Mice Inventions.

2.5 New Regeneron Patent Rights.

If Regeneron acquires rights to additional intellectual property from a Third Party required by Company for its use of the Mice or Regeneron Technology under this Agreement that requires no payments to such Third Party and that permits Regeneron to include such intellectual property in the scope of the license grants in Section 2.1 of this Agreement, such intellectual property shall be included in this Agreement at no additional charge to Company. In the event that Regeneron acquires rights to such additional intellectual property from a Third Party relating to the Mice or Regeneron Technology pursuant to an agreement that requires payments to such Third Party and that permits Regeneron to include such intellectual property in the scope of the license grants in Section 2.1 of this Agreement, Regeneron and Company shall negotiate in good faith the terms under which such intellectual property shall be included in this Agreement, including without limitation, additional payments to be made by Company for the right to use such intellectual property. Such additional payments (including, without limitation, pass through royalties) shall not exceed the payments required to be made by Regeneron to such Third Party in consideration for Controlling and sublicensing the intellectual property rights. **********. In the event Regeneron and Company are unable to agree on such terms, then the subject matter of such intellectual property shall not be included within the definition of Regeneron Technology, and Company shall have no license or rights with respect to such intellectual property.

2.6 Prohibited Uses. Notwithstanding Section 2.1, Company agrees, for itself and on behalf of its Affiliates, that it and they shall not Derive Mice, Mice Materials, Antibodies or Antibody Materials for any Third Party as a contractor or service provider of such Third Party.

ARTICLE III
MATERIAL TRANSFER; OWNERSHIP OF MICE

3.1 Technology Transfer. Subject to Section 3.5, Regeneron shall transfer to Company the materials, including Regeneron Know-How and Mice, set forth on Exhibit A. Subject to Section 8.1, all such Regeneron Know-How and Mice listed in Exhibit A shall be considered Confidential Information. Other than the grant of license in Section 2.1, Regeneron retains all right, title and interest in and to the Regeneron Technology, Mice, and Mice Materials described in Exhibit A. Except as set forth in this Article III, Regeneron shall not have any obligation to provide to Company any trade secrets, know-how, information, specifications, protocols or procedures.

3.2 Transition Support. The Parties agree to work diligently and in good faith to complete the transfers set forth in Section 3.1 from Regeneron to Company as soon as reasonably practicable. Regeneron, at its sole cost and expense, shall provide reasonable telephonic assistance to Company to help identify and solve issues relating to unsuccessful breeding of Mice (including ********** **********). At Company's request and expense, upon reasonable prior notice and at mutually convenient dates, Regeneron personnel shall **********to help identify and solve issues relating to unsuccessful breeding of Mice at the Site designated by Company.

3.3 Delivery Terms and Conditions. Regeneron shall be responsible for (a) making arrangements for all Mice identified in Exhibit A to be shipped from Regeneron to Company or any Approved Third Party; Regeneron shall take reasonable steps to ensure that all Mice shall be free of any pathogen prior to shipment; (b) the proper packaging of Mice, such packaging to comply with Applicable Law and Regeneron's veterinary handling procedures and protocols; and (c) shipment of all such Mice. All Mice identified in Exhibit A will be shipped ********** to such Sites as Company may designate from time to time (Incoterms 2000). The Mice to be shipped promptly following the Effective Date pursuant to Section 1.35 shall be sent to the Site designated by Company. Company shall be required to notify Regeneron of the Site for the delivery of Mice pursuant to this Section 3.3 **********. Company shall provide Regeneron with prompt written notice of the date that is the Transfer Date. Company shall be responsible for (y) paying all shipment and delivery charges and import or export duties in connection therewith and (z) complying with all customs regulations and obtaining any and all permits, forms or permissions that may be required for Company to accept shipment of such Mice from Regeneron.

3.4 Failure to Produce Progeny. Company shall be responsible for establishing a colony of Mice. ********** **********

3.5 Ownership of Mice and Mice Materials; Assignment. Company agrees, for itself and on behalf of its Affiliates, that Regeneron retains all right, title and interest in the Mice and Mice Materials. Without limiting the foregoing, Company hereby assigns, for itself and on behalf of its Affiliates, to Regeneron any right, title and interest it or they may have in Progeny and Mice Materials. Company agrees, for itself and on behalf of its Affiliates, to execute any and all further instruments, forms of assignments and other documents, and to take such further actions as

Regeneron may reasonably request at Regeneron's cost, in order to transfer all of Company's (and/or its Affiliates) rights, if any, in Mice (including, without limitation, Progeny) and Mice Materials to Regeneron and on such transfer any such rights shall be included in Regeneron Technology and subject to the licenses granted pursuant to Section 2.1. During the term of this Agreement, it is agreed that (i) Company shall have the right to transfer the Mice and Mice Materials to Sites solely for purposes of this Agreement, and (ii) Company, its Affiliates and Approved Third Parties may use Mice (including, without limitation, Progeny) and Mice Materials only in the manner contemplated by Section 2.1.

3.6 Approved Third Party. Company may use Approved Third Party service providers (a) to have Mice made solely by means of breeding Mice with other Mice in accordance with the terms of the license grant in Section 2.1(a); and (b) to have Mice or Mice Materials made or used in accordance with the license grants in Sections 2.1(b) and 2.1(c), in each case, under the following conditions: (i) Regeneron shall within thirty (30) days of receiving written notice from the Company of the identity of the relevant Third Party and such other information as Regeneron may reasonably require to assess such appointment have notified Company in writing whether such Third Party is approved or not (such approval not to be unreasonably withheld or delayed); and (ii) such Third Party service provider shall have entered into a separate writing with Regeneron substantially in the form annexed hereto as Exhibit C. Company shall remain responsible for the performance of its Approved Third Party with the obligations of Company under this Agreement and shall ensure that any such Approved Third Party does not commit any act (including any act of omission) which Company is prohibited from committing directly and commits such acts as Company is obligated to hereunder.

ARTICLE IV
PAYMENTS AND RECORDS

4.1 Up-Front Fee/Annual Fees. Company shall pay Regeneron a non-refundable amount of twenty million United States dollars (US$20,000,000) within seven (7) days of the execution of this Agreement. In addition, Company shall pay Regeneron a non-refundable amount of twenty million United States dollars (US$20,000,000) on each of the first, second, and third anniversaries of the Transfer Date. Company shall pay to Regeneron the Adjusted Annual Fee on each of the fourth and fifth anniversaries of the Transfer Date unless this Agreement shall have been terminated prior to the fourth anniversary of the Transfer Date in accordance with Section 9.2. All payments to be made pursuant to this Section 4.1 shall be made by bank wire transfer in immediately available funds to an account designated by Regeneron.

4.2 Royalties. Subject to Section 4.3, Company shall pay royalties to Regeneron on aggregate worldwide Net Sales of all Subject Products sold during the Royalty Term. **********. Payments due under this section shall be due in each calendar quarter in arrears, and shall be paid no later than sixty (60) days after the last business day of each such calendar quarter. An example of **********is set forth on Schedule 4.2 for purposes of illustration.

4.3 Royalty Term. The royalties payable under Section 4.2 shall be paid to Regeneron for the period of time, as determined on a Subject Product by Subject Product and country-by-country basis, commencing on the Effective Date and ending on the later of (a)

********** after the Launch of a given Subject Product in a given country and (b) the expiration of the last Valid Claim of Royalty Bearing Company Patent Rights claiming or covering such Subject Product in such country (the "Royalty Term"). For the avoidance of doubt, the Royalty Term may extend beyond the term of this Agreement. As used above, the term "Royalty Bearing Company Patent Rights" shall mean with respect to an Antibody either (a) all issued patents in a country owned or Controlled by Company and/or its Affiliates, in each case, which includes a Valid Claim claiming the composition of such **********, or (b) if a patent described in (a) above never issues in a country, then the first issued patent in such country that is owned or Controlled by Company and/or its Affiliate with a Valid Claim claiming ********** or any approved use of such an Antibody (**********) in a country.

4.4 Reports. Company shall keep and maintain, and shall cause its Affiliates and Licensees to keep and maintain, records and books of account, in accordance with generally accepted accounting practices, detailing full written accountings of Net Sales of Subject Products subject to royalty obligations to Regeneron, and all other information necessary for the accurate determination of royalty payments (including, without limitation, currency conversion rate methodologies). Company shall deliver to Regeneron each calendar quarter commencing upon the first calendar quarter following the first sale of a Subject Product, a report detailing the information on which the royalty payments were calculated, including a breakdown of Net Sales of each Subject Product on a country-by-country basis, which report shall accompany the royalty due under Section 4.2. Furthermore, for each Subject Product, Company shall notify Regeneron in writing promptly following (a) the date on which Company first initiates a Phase 2 trial (as defined in 21 CFR 312.21(b), as amended from time to time) (or a Phase 3 trial (as defined in 21 CFR 312.21(c), as amended from time to time), if no Phase 2 trial is conducted) of a Subject Product, and (b) each receipt, on a country-by-country basis, by Company (or by any of its Affiliates or Licensees) of regulatory approval to market and sell Subject Products.

4.5 Records and Audits.

(a) Company shall keep, and shall cause its Affiliates and Licensees to keep, complete and accurate records of the latest three (3) years relating to gross sales, Net Sales, and all information reasonably relevant under Sections 4.2 and 4.3. For the sole purpose of verifying amounts payable to Regeneron, Regeneron shall have the right, no more than once each calendar year, to review such records, through independent certified public accountants proposed by Regeneron and reasonably acceptable to Company (such consent not to be unreasonably withheld or delayed), upon fifteen (15) days' prior written notice. The accounting firm shall disclose to Regeneron and Company only whether the royalty reports are correct and details concerning any discrepancies, but no other information shall be disclosed to Regeneron.

(b) If any review pursuant to Section 4.5(a) reflects an underpayment to Regeneron, such underpayment shall be promptly remitted to Regeneron, together with interest calculated in the manner provided in Section 4.8. If the underpayment is equal to or greater than five percent (5%) of the amount that was otherwise due for any calendar quarter, Regeneron shall be entitled to have Company pay all of the reasonable costs of

such review otherwise such costs will be paid by Regeneron. If the review reflects an overpayment by Company, then, at Company's option, such overpayment shall either be promptly refunded to Company by Regeneron or creditable against amounts payable by Company in subsequent payment periods.

4.6 United States Dollars (or U.S.dollars). All dollar ($) amounts specified in this Agreement are United States (U.S.) dollar amounts.

4.7 Currency Exchange. With respect to sales of Subject Products invoiced in a currency other than U.S. dollars and other amounts received by Company, Company's Affiliates and/or Licensees in a currency other than U.S. dollars, such amounts shall be expressed in their local currency and in their U.S. dollar equivalents calculated using the exchange rate conversion methodology then in consistent use by Company throughout its business in accordance with generally accepted accounting principles and used in its preparation of the financial statements filed with the SEC (or similar regulatory agency in another country if no financial statements are filed with the SEC).

4.8 Late Payments. Company shall pay interest to Regeneron on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of (a) ****** above LIBOR; or (b) the highest rate permitted by Applicable Law, calculated on the number of days such payments are received by Regeneron after the date such payments are due. In addition, Company shall reimburse Regeneron for all costs and expenses, including without limitation reasonable attorney fees and legal expenses, incurred in the collection of late payments. For the purposes of this Agreement, LIBOR shall mean the London Interbank Offered Rate as calculated by the British Bankers' Association or, if LIBOR ceases to be available, the base rate of a London bank selected by Regeneron.

4.9 No Set Off. Except as set forth in Section 4.10, (a) neither Party shall set off any of its obligations against or otherwise withhold from, any amount payable by it to the other Party hereunder without the other Party's prior written consent and (b) there shall be no deduction or withholding from the amounts payable hereunder.

4.10 Taxes.

(a) General. The royalties and other amounts payable by Company to Regeneron pursuant to this Agreement ("Payments") shall not be reduced on account of any taxes unless required by Applicable Law. Regeneron alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be paid by Company) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Company shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Regeneron is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Company or the appropriate governmental authority (with the assistance of Company to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Company of its

obligation to withhold tax, and Company shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, provided that Company has received evidence, in a form satisfactory to Company, of Regeneron's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, Company withholds any amount, it shall pay to Regeneron the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to Regeneron proof of such payment within sixty (60) days following that payment.

(b) Indirect Taxes. Notwithstanding anything contained in Section 4.10(a), this Section 4.10(b) shall apply with respect to value added taxes, sales taxes, consumption taxes and other similar taxes ("Indirect Taxes"). All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, Company shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by Regeneron in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate.

(c) Changes Following Assignment. If following an assignment of this Agreement under Section 10.1 the treatment of any Payments or Indirect Taxes for either Party is affected by the assignment, then the Parties shall use their best efforts to promptly negotiate a provision in replacement of the affected sections of this Agreement that is consistent with and achieves as nearly as possible the original treatment of such Payments and Indirect Taxes immediately prior to any such assignment.

ARTICLE V
REPRESENTATIONS AND WARRANTIES; COVENANTS

5.1 Representations and Warranties of Company. Company represents and warrants as follows:

(a) Company is validly incorporated under the laws of Japan;

(b) Company has the corporate and legal right, authority and power to enter into this Agreement and to perform its obligations hereunder;

(c) Company has taken all necessary action to authorize the execution, delivery and performance of this Agreement;

(d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Company, enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law); and

(e) the performance of Company's obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party.

5.2 Representations and Warranties of Regeneron. Regeneron represents and warrants to Company that, subject to the terms of Schedule 5.2,

(a) Regeneron is a corporation duly organized, validly existing and in good standing under the laws of the State of New York, United States of America;

(b) Regeneron has the corporate and legal right, authority and power to enter into this Agreement and to perform its obligations hereunder;

(c) Regeneron has taken all necessary action to authorize the execution, delivery and performance of this Agreement;

(d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Regeneron, enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

(e) the performance of Regeneron's obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party;

(f) Regeneron has the right to grant the licenses granted to Company on the terms set forth herein;

(g) as of the Effective Date and with no further duty to update (except pursuant to Section 7.3), (i) there is no pending litigation that alleges that any of Regeneron's activities directly relating to the Regeneron Technology, Mice, or Mice Materials have violated, or would violate, any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation); and (ii) to its knowledge, no litigation has been otherwise threatened which alleges that any of its activities directly relating to the Regeneron Technology, Mice, or Mice Materials have violated or would violate, any of the intellectual property rights of any Third Party;

(h) Regeneron has disclosed or made available to Company all the Regeneron Technology needed for Company to make and use "VelocImmune 2" Mice pursuant to Section 2.1 (a) and (b) of this Agreement;

(i) to its knowledge, Company's use of the Mice and other Regeneron Technology generally hereunder (but not with respect to a specific Antibody or antigen or any methods relating to Antibody or Antibody Material generation) will not infringe or otherwise violate any Third Party patent issued ********** claiming

genetically modified mice or the use thereof to make antibodies. **********.

(j) to its knowledge, the issued patents included in the Regeneron Technology existing at the Effective Date are not invalid or unenforceable in whole or part;

(k) to its knowledge, the development or reproduction of the Mice or the conception, development and reduction to practice of the Regeneron Technology existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other rights of any Person; and

(l) to its knowledge, the Know-How listed or referred to in Exhibit A is sufficient to establish a colony of Mice.

For purposes hereof, "to its knowledge" shall mean actual knowledge with no duty of inquiry or investigation

5.3 Disclaimer of Warranty. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, ALL REGENERON TECHNOLOGY AND MICE ARE PROVIDED TO COMPANY (a) "AS IS" AND WITHOUT ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, TITLE OR FITNESS FOR A PARTICULAR PURPOSE AND (b) WITHOUT ANY REPRESENTATION OR WARRANTY THAT THE USE OF REGENERON TECHNOLOGY OR MICE WILL NOT INFRINGE ANY THIRD PARTY'S PATENT OR OTHER RIGHT.

5.4 Covenants. Company agrees, for itself and on behalf of its Affiliates, that it and they:

(a) will abide by all industry accepted guidelines applicable to the use, handling and disposal of genetically modified animals and comply in all material respects with all Applicable Laws which relate to the use of the Mice and Mice Materials;

(b) will use diligent efforts to ensure that the Mice do not come into contact with any mice other than Mice; and in particular will not intentionally or recklessly breed Mice with any mice other than Mice, except as specifically set forth in the last sentence of this Section 5.4;

(c) will not make any heritable genetic modifications to the Mice;

(d) will not Derive embryonic or other stem cells from the Mice or other Mice Material that could be used to make Mice;

(e) will not use Mice or Mice Materials to directly manufacture or produce Subject Products for sale. For the avoidance of doubt, Regeneron acknowledges that Company may (i) isolate cDNA from Mice which code for a given antibody (the "Isolated Mice Sequences"), (ii) modify DNA sequences of cell lines derived from sources other than the Mice and mice to incorporate the Isolated Mice Sequence or modifications

thereof, and (iii) manufacture Subject Products for sale using such modified cell lines or using other Antibody Materials and such use shall not constitute a breach of Section 5.4(e);

(f) will not use Mice Materials to create Mice, mice or any transgenic animals; and

(g) will ensure that all Mice (including Progeny) and Mice Material supplied to it or Derived under this Agreement remain in the possession of Company, its Affiliates or Approved Third Parties.

**********.

ARTICLE VI
INDEMNIFICATION

6.1 Indemnification by Company. Company agrees to indemnify and hold harmless Regeneron and Regeneron's Affiliates and their respective shareholders, directors, officers, employees and agents ("Regeneron Indemnitees") from and against any liabilities, losses, costs, damages, fees or expenses arising out of any Third Party claim relating to (a) any breach by Company or any of its Affiliates or Approved Third Parties of any of its representations, warranties or obligations pursuant to this Agreement (or, in the case of the Approved Third Party, the letter agreement with Regeneron in the form annexed hereto as Exhibit C), (b) any product liability, personal injury, property damage or other damage resulting from the testing, manufacture, use, offer for sale, sale or importation of Antibodies, Antibody Materials, or Subject Products, or (c) infringement or misappropriation of any patent or other intellectual property rights of any Third Party (other than Third Party patents specifically covering Regeneron Technology, such patents being referred to as "Regeneron Technology Blocking Patents") resulting from the manufacture, use, offer for sale, sale or importation of Antibodies, Antibody Materials, or Subject Products, by Company or Company's Affiliates, Licensees, Distributors, Approved Third Parties or contract manufacturers, provided, however, that Company shall not be obligated to indemnify or hold harmless Regeneron Indemnitees from any such liabilities, losses, costs, damages, fees or expenses to the extent that (i) such liabilities, losses, costs, damages, fees or expenses have resulted from the grossly negligent (or more culpable) act or omission of a Regeneron Indemnitee or (ii) Regeneron has an obligation to indemnify any Company Indemnitee pursuant to Section 6.2 in respect of such liabilities, losses, costs, damages, fees or expenses.

6.2 Indemnification by Regeneron. Regeneron agrees to indemnify and hold harmless Company and Company's Affiliates, Approved Third Parties, Company's contract manufacturers of Subject Products, Distributors, and Licensees, and their respective shareholders, directors, officers, employees and agents ("Company Indemnitees") from and against any liabilities, losses, costs, damages, fees or expenses arising out of any Third Party claim relating to any breach by Regeneron of any of its representations, warranties or obligations pursuant to this Agreement; provided, however, that Regeneron shall not be obligated to indemnify or hold harmless Company Indemnitees from any such liabilities, losses, costs, damages, fees or expenses to the extent that such liabilities, losses, costs, damages, fees or expenses have resulted from the grossly negligent (or more culpable) act or omission of a Company Indemnitee.

6.3 Claims for Indemnification. A Person entitled to indemnification under this Article VI (an "Indemnified Party") shall give prompt written notification to the Person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third-Party claim as provided in this Section 6.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within thirty (30) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all reasonable and verifiable out-of-pocket costs, including attorney fees, incurred by the Indemnified Party in defending itself within sixty (60) days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable and verifiable fees and expenses of counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, delayed or conditioned.

ARTICLE VII
INTELLECTUAL PROPERTY PROTECTION AND RELATED MATTERS

7.1 Ownership of Intellectual Property.

(a) Subject to the license grants to Company under Section 2.1 and the ownership and assignment provisions in Section 2.4 and Section 3.5, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all information, improvements and inventions that are conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership, by or on behalf of such Party (or its Affiliates or its licensees (excluding, in the case of Regeneron, Company, its Affiliates and Licensees) under or in connection with this Agreement, whether or not patented or patentable, and any and all Patent Rights and intellectual property rights with respect thereto. Determination of authorship, inventorship or ownership shall be made in accordance with applicable United States law.

(b) Except as specifically set forth herein, Regeneron and Regeneron's Affiliates shall retain all right, title and interest in and to all Regeneron Technology.

(c) Company and Company's Affiliates shall retain all right, title and interest in and to (i) all Antibodies, Antibody Materials and Subject Products and (ii) subject to Section 2.4,Section 3.5, and Article VIII, all results, technical information, inventions, materials and data, and any intellectual property rights therein, or otherwise resulting from Company's or Company's Affiliates use of (A) the Mice, Mice Materials and other Regeneron Technology in accordance with this Agreement, or (B) Antibodies, Antibody Materials and Subject Products ("Company Know-How").

7.2 Prosecution of Patent Rights.

(a) Regeneron shall have the right and option (but not the obligation) to file and prosecute any patent applications and to maintain any patents within the Regeneron Patent Rights in Regeneron's name, and to control any interferences, reissue proceedings and re-examinations relating thereto; provided, however, that, Regeneron shall use commercially reasonable efforts (i) to prosecute the patent applications listed in Exhibit B in **********, and (ii) to maintain the patents listed in Exhibit B and the patents resulting from the patent applications listed in Exhibit B in **********.

(b) Company shall have the right and option (but not the obligation) to file and prosecute any patent applications and to maintain any patents within the Company Patent Rights in Company's name, and to control any interferences, reissue proceedings and re-examinations relating thereto.

7.3 Infringement. Company shall promptly report in writing to Regeneron during the term of this Agreement any (a) known or suspected infringement of any of the Regeneron Patent Rights, or (b) unauthorized use of any of the Regeneron Know-How of which the Company becomes aware. In the event that either Party or any of its Affiliates shall receive written notice from a Third Party claiming that the Mice, Mice Materials or Regeneron Technology infringes or otherwise violates the intellectual property rights of such Third Party, then such Party shall promptly notify the other Party in writing of this notice of infringement. Regeneron shall promptly report to Company the initiation of any formal legal proceedings during the term of this Agreement claiming the infringement of or unauthorized use of any Regeneron Patent Rights or Regeneron Know-How.

7.4 Enforcement. Regeneron shall have the sole right to initiate a suit or take other appropriate action that it believes is reasonably required to protect Regeneron Patent Rights from any known or suspected infringement or to prevent the unauthorised use or disclosure of Regeneron Know-How. Company shall have the sole right to initiate a suit or take other appropriate action that it believes is reasonably required to protect Company Patent Rights from any known or suspected infringement or to prevent the unauthorised use or disclosure of any Company Know-How.

7.5 Defense. In the event that a Third Party asserts, as a defense or as a counterclaim in any infringement action under Section 7.4 or in a declaratory judgment action or similar action or claim filed by such Third Party, that Regeneron Patent Rights are invalid or unenforceable, Regeneron shall have the sole right, but not the obligation, through counsel of its choosing, to respond to such defense or defend against such counterclaim, action or claim (as applicable), including the right to settle or otherwise compromise such claim.

7.6 Third Party Litigation. Notwithstanding Section 7.4 or Section 7.5, in the event of any actual or threatened suit against Company, or its Affiliates, Licensees, distributors or customers alleging that the use of Regeneron Technology, the Mice, Mice Materials, Antibodies or Antibody Materials or the Exploitation of Subject Products by or on behalf of Company under this Agreement infringes the Patent Rights or other intellectual property rights of any Person (an "Infringement Suit"), Company shall be solely responsible for assuming direction and control of the defense of claims arising therefrom (including the right to settle such claims at its sole discretion), unless Company is seeking indemnification under the terms of Section 6.2.

7.7 Co-operation. Each Party shall provide to the other all reasonable assistance requested by the other Party (and at the other Party's reasonable expense) in connection with any action claim or suit under this Article VII, including allowing access to the other Party's files and documents and to such other Party's personnel who may have possession of relevant information.

7.8 Recoveries.

(a) With respect to any suit or action to protect Regeneron Technology brought or taken by Regeneron, Regeneron shall retain one hundred percent (100%) of any recovery obtained by it as a result of any suit or action to protect Regeneron Technology.

(b) With respect to any suit or action to protect Company Technology brought or undertaken by Company or its Affiliate, Company shall retain one hundred percent (100%) of any recovery obtained by it as a result of or in connection with any such suit or action to protect Company Technology; provided that to the extent that such recovery includes royalty amounts otherwise payable to Regeneron hereunder during the Royalty Term, Company shall pay to Regeneron the royalty amounts calculated in accordance with Section 4.2 based on the estimated Net Sales corresponding to the recovered lost profits. ********** **********.

ARTICLE VIII
CONFIDENTIALITY

8.1 Definition of Confidential Information. Subject to the last paragraph in this Section 8.1, Confidential Information includes all information, data and know-how disclosed by either Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") hereunder, whether orally or as embodied in tangible materials, including research, inventions, discoveries, writings, drawings, graphs, charts, photographs, recordings, designs, plans, processes, models, technical information, facilities, methods, assays, data, chemical formulas, compositions, compounds, instrumentation, trade secrets, copyrights, systems, patents, patent applications, procedures, manuals, specifications, prototypes, samples, structures, models,

any other intellectual property, and confidential reports. Notwithstanding the foregoing, Confidential Information shall not include information which the Receiving Party can demonstrate is:

(a) already in the possession of the Receiving Party, without obligation of confidentiality, at or before the time of disclosure hereunder as shown by the Receiving Party's files existing at the time of disclosure; or

(b) now or hereafter becomes publicly known through no wrongful act of the Receiving Party (provided that if Confidential Information becomes publicly known this shall not excuse a prior disclosure by the Receiving Party); or

(c) lawfully received by the Receiving Party from a Third Party not under an obligation of confidence to the Disclosing Party; or

(d) developed by the Receiving Party independent of the Confidential Information received hereunder; or

(e) approved for release by written authorization of the Disclosing Party.

Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of either Person merely because individual elements thereof are in the public domain or in the prior possession of a Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of that Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of a Person.

Notwithstanding anything to the contrary in this Section 8.1, Company's Confidential Information shall be limited to (i) confidential information in the reports delivered to Company in accordance with Section 4.4, (ii) confidential information discovered by Regeneron during any Site visit in accordance with Section 3.2, (iii) confidential information discovered by Regeneron during any audit conducted pursuant to Section 4.5, (iv) confidential information provided to Regeneron in connection with any claim for indemnification under ARTICLE VI, (v) confidential information provided to Regeneron pursuant to Section 7.7, (vi) confidential information related to Approved Third Parties disclosed to Regeneron pursuant to Section 3.6, and (vii) information disclosed by prior mutual agreement specifically certified by Company as being confidential prior to its disclosure, in each case, unless such information falls under the exceptions described in clause (a), (b), (c), (d), or (e) above in this Section 8.1. All other information, data or know-how disclosed by Company or its Affiliates hereunder shall be non-confidential and shall not be subject to the confidentiality obligations and restrictions on use in this Article VIII.

8.2 Confidentiality and Non-Use Obligations. Each Party agrees, subject to Section 8.4, that it will hold in strict confidence and not disclose, disseminate or distribute to any Third Party Confidential Information received from the Disclosing Party and use such Confidential

Information for no purpose other than those contemplated by this Agreement. Each Party agrees that access to Confidential Information will be limited to its Affiliates, Licensees and its Approved Third Parties (in each case, which are bound by the confidentiality obligations herein), as well as such Party's and its Affiliates', Licensees' and Approved Third Parties' employees (including temporary staff), agents, or other authorized representatives who: (a) need to know such Confidential Information in connection with their work and (b) have signed agreements obligating them to maintain the confidentiality of the Confidential Information, provided that each Party shall remain responsible for any failure by its Affiliates, Licensees and Approved Third Parties and their respective employees (including temporary staff), consultants, advisors, to treat such information and materials as Confidential Information. Each Party further agrees to inform such employees (including temporary staff), agents or authorized representatives of the confidential nature of Confidential Information received from the Disclosing Party and agrees to take all necessary steps to ensure that the terms of this Agreement are not violated by them.

8.3 Loss of Confidential Information. Each Party shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information received from the Disclosing Party and shall exert at least the same degree of care as it uses to protect its own Confidential Information. Each Party shall immediately notify the other in the event of any actual or suspected loss or unauthorized disclosure of that Party's Confidential Information. Each Party will take all reasonable further steps requested by the other Party to prevent, control or remedy such violation.

8.4 Permitted Disclosure. Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction or other competent authority; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash any such order or obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in response to such court or governmental order;

(b) otherwise required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body; provided, however, that the Receiving Party shall (i) provide the Disclosing Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (ii) if requested by the Disclosing Party, seek confidential treatment with respect to any such disclosure to the extent available, and (iii) consider in good faith the comments of the Disclosing Party in any such disclosure or request for confidential treatment; or

(c) made by Company, its Affiliates or Licensees to a regulatory authority in connection with any filing, application or request for any approval, license, registration or authorization relating to a Subject Product; provided, however, that Company will (i)

provide Regeneron with reasonable advance notice of and an opportunity to comment on any such required disclosure, (ii) seek confidential treatment with respect to any such disclosure to the extent available, and (iii) consider in good faith the comments of Regeneron in any such disclosure or request for confidential treatment;

8.5 Return of Confidential Information. Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to Section 8.6, upon termination or expiration of this Agreement, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the Receiving Party also shall certify in writing that it has satisfied its obligations under this Section 8.5 within ten (10) days of a written request by the Disclosing Party.

8.6 Retention of Confidential Information by Company. Section 8.5 shall not apply to Regeneron Confidential Information during the term of this Agreement or on the expiry or termination of this Agreement if and to the extent that Company's rights under the Regeneron Technology survive such termination or expiry pursuant to Section 9.4.

8.7 Publicity. During the term of this Agreement, the content of any press release or public disclosure relating to this Agreement shall be mutually agreed by the Parties, which agreement shall not be unreasonably withheld, delayed or conditioned, except that a Party may, without the other Party's agreement, (a) issue such press release or make such public disclosure if the contents of such press release or public disclosure have previously been made public other than through a breach of this Agreement by the issuing Party or (b) subject to Section 8.4 issue such press release or make such public disclosure if such press release or public disclosure is required by Applicable Law, regulation or legal process, including without limitation by the rules or regulations of the SEC (or similar regulatory agency in a country other than the United States) or of any stock exchange or other securities trading institution. It is the intent of the Parties to issue one press release announcing the execution of this Agreement. In any press releases issued by Company regarding the discovery, development or approval of a Subject Product, Antibody or Antibody Materials, Company shall include a statement regarding the role of Regeneron Technology and Mice, which statement shall be reasonably acceptable to Regeneron. The Parties shall issue a joint press release on the Effective Date with respect to the execution of this Agreement in the form annexed hereto as Exhibit D.

8.8 Disclosure of Provisions of Agreement.

(a) Subject to Sections 8.7 and 8.8(b), each Party agrees to hold as confidential the terms of this Agreement that have not been disclosed publicly except that (i) each Party shall have the right to disclose such terms to investors, potential investors, lenders, potential lenders, acquirers, potential acquirers, investment bankers and other Third Parties in connection with financing and acquisition activities, provided that any such Third Party has entered into a written obligation with the disclosing Party to treat such information and materials as confidential which is at least as stringent as the conditions

imposed by this Agreement and (ii) each Party shall have the right to disclose such terms as required by applicable law, regulation or legal process, including without limitation by the rules or regulations of the SEC (or similar regulatory agency in a country other than the United States) or of any stock exchange or other securities trading institution.

(b) In the event that this Agreement shall be included in any report, statement or other document filed by either Party or an Affiliate of either Party with the SEC or similar regulatory agency in a country other than the United States or any stock exchange or other securities trading institution, such Party shall consider in good faith any requests for confidential treatment as may be reasonably requested by the other Party.

8.9 Approvals. Each Party shall submit any press release or any disclosure requiring the other Party's approval pursuant to this Article VIII to the other Party, and the Party receiving such request shall have three (3) business days to review and approve any such press release or disclosure, which approval shall not be unreasonably withheld. If the Party receiving such request does not respond in writing within such three (3) business day period, the press release or disclosure shall be deemed approved. In addition, if a public disclosure is required by law, rule or regulation, including without limitation in a filing with the Securities and Exchange Commission, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure for the non- disclosing Party's prior review and comment, which comments shall be considered in good faith by the disclosing Party.

8.10 Term. All obligations of confidentiality imposed under this Article VIII shall only survive the expiration or early termination of this Agreement for a period of seven (7) years.

ARTICLE IX
TERM AND TERMINATION

9.1 Term. The term of this Agreement shall commence on the Effective Date and, subject to the last sentence of Section 9.2 (d), shall expire on the sixth anniversary of the Transfer Date unless earlier terminated under the terms of this Agreement. For the avoidance of doubt, Company shall have the right but not the obligation to terminate this Agreement without cause upon written notice prior to the fourth anniversary of the Transfer Date in accordance with Section 9.2(a).

9.2 Termination.

(a) Convenience. Company may elect to terminate this Agreement at any time by providing ninety (90) days' prior written notice to Regeneron. If such notice is sent with an effective date of termination prior to the fourth anniversary of the Transfer Date, such notice shall be accompanied (or preceded) by the payment of all sums which were not previously paid and which have become or would have become due and payable pursuant to the first or second sentence of Section 4.1 but for the termination under this Section

9.2(a). For example, if the Transfer Date is April 30, 2007 and Company pays to Regeneron twenty million United States dollars (US$20,000,000) on April 30, 2007 and on July 15, 2007 delivers a notice of termination with an effective date of termination on October 15, 2007, Company would be obligated to pay to Regeneron on July 15, 2007 sixty million United States dollars (US$60,000,000) representing twenty million United States dollars (US$20,000,000) that would have otherwise been payable on April 30, 2008, plus twenty million United States dollars (US$20,000,000) that would otherwise have been payable on April 30, 2009, plus twenty million United States dollars (US$20,000,000) that would have otherwise been payable on April 30, 2010. However, for example, if the Transfer Date is April 30, 2007 and Company has paid all amounts previously due and payable under Section 4.1 and on July 15, 2010 delivers a notice of termination with an effective date of termination on October 15, 2010, Company would not be obligated to pay to Regeneron any further sums pursuant to Section 4.1. If such notice of termination under this Section 9.2(a) is sent with an effective termination date on or after the fourth anniversary of the Transfer Date, such notice shall be accompanied (or preceded) by the payment of all sums which were not previously paid and which have become or would have become due and payable pursuant to the first, second, or third sentence of Section 4.1 but for the termination under this Section 9.2(a). For example, if the Transfer Date is April 30, 2007 (and Company has paid all amounts previously due and payable under Section 4.1) and on June 20, 2011 Company delivers a notice of termination with an effective date of termination on September 20, 2011, Company would be obligated to pay Regeneron on June 20, 2011 twenty million United States dollars (US$20,000,000), as adjusted to reflect the Adjusted Annual Fee pursuant to the terms of the third sentence of Section 4.1, representing the Adjusted Annual Fee that would have otherwise been payable on April 30, 2012.

(b) Breach. Either Party shall have the right (but not the obligation) to terminate this Agreement upon written notice to the other Party if the other Party materially breaches or defaults in the performance of any of the provisions of this Agreement; provided that such material breach or default has not been cured (if capable of being cured) within sixty (60) days after the giving of notice by the first Party specifying such breach or default. For purposes of this Section 9.2(b), the term "material breach" shall mean a breach or default in performance hereunder by a Party that substantially undermines the contractual rights, protections or benefits of the non-breaching Party under this Agreement.

(c) Technical Event. Company may terminate this Agreement upon providing thirty (30) days prior written notice to Regeneron together with adequate written records to document its claim of the occurrence of a Technical Event. Such records shall be subject to review by an independent Third Party expert designated by Regeneron within ten (10) business days of receipt of the written notice of termination and approved by Company, such approval not to be unreasonably withheld or delayed. Such expert shall review such written records and promptly determine whether or not a Technical Event has occurred. The expert's decision shall be final and binding upon the Parties as to this issue. Following the provision of any such notice of termination all obligations to make payments due under this Agreement by the Company to Regeneron shall be suspended from the date of such notice until the date of the publication of the expert's determination. Any notice of

termination shall be deemed effective from the date of the notice of termination in the event that the expert determines that a Technical Event has occurred. As used above, the term "Technical Event" shall mean, **********.

(d) **********. **********.

9.3 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Regeneron are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter "IP"). The Parties agree that Company, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Regeneron under the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, Company shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of such IP, which, if not already in Company's possession, shall be promptly delivered to it upon Company's written request therefor.

9.4 Effects of Termination.

(a) Termination or Expiration of License. Except as set forth below in this Section 9.4, upon expiration or termination of this Agreement, the licenses granted by Regeneron to Company under Section 2.1 shall terminate and revert to Regeneron as of the effective date of such expiration or termination. Subject to the terms of the last sentence of Section 9.4(c), upon termination of this Agreement for any reason, Company may continue to use and Exploit any Antibodies, Antibody Materials and Subject Products generated pursuant to this Agreement and Company shall pay royalties during the Royalty Term in accordance with Article IV. Upon termination of this Agreement by Company in accordance with Section 9.2(b), 9.2(c), or 9.2(d), Company shall not be required to make any further payments to Regeneron under Section 4.1, except that neither Party shall be relieved of any obligations arising prior to such termination, including any payment obligations which arose and are due with respect to any period prior to such termination. Upon termination of this Agreement by Regeneron in accordance with Section 9.2(b), (i) in addition to any other amounts payable by Company to Regeneron under this Agreement, under law or pursuant to any contractual remedies available to Regeneron (but giving full allowance in due course for any sums paid hereunder), Company shall pay the amounts otherwise payable by Company under Section 9.2(a) as if Company had terminated this Agreement for convenience, and (ii) Regeneron may seek equitable remedies from a court of competent jurisdiction, including, if appropriate, destruction of Antibodies and Antibody Materials.

(b) Discontinuation of Use; Return of Material. Upon expiration of the term of the Agreement or earlier termination of this Agreement, Company (and its Affiliates and, if applicable, Approved Third Parties) will discontinue use of Regeneron's Confidential Information as of the effective date of such expiration or termination, except to the extent

that such use of such Confidential Information is reasonably necessary for the Company to continue to use and Exploit all Antibodies and Antibody Materials generated using the Mice and Mice Materials prior to the date of expiration or termination, subject to Company's obligations to pay royalties to Regeneron during the Royalty Term pursuant to Article IV, and if requested by Regeneron will return Regeneron's Confidential Information to which Company does not retain any rights hereunder in accordance with Section 8.5.

(c) Destruction of Mice and Mice Materials; Treatment of Antibodies and Antibody Materials. Except as set forth in paragraph (d) below, within ten (10) business days after the effective date of expiration or termination of this Agreement for any reason, Company shall destroy (or cause the destruction of) all Mice (including any Progeny) and Mice Materials held by Company, its Affiliates and, if applicable, Approved Third Parties. Within seven (7) days of destruction, an officer of Company shall deliver to Regeneron a signed letter, in form and substance reasonably acceptable to Regeneron and the Company, certifying that all Mice (including, without limitation, any Progeny) and, if applicable, Mice Materials have been destroyed. Except as set forth in the next sentence, upon expiration or termination of this Agreement for whatever reason, Company shall have the right to continue to use and Exploit all Antibodies and Antibody Materials generated using the Mice and Mice Materials prior to the date of termination, subject to Company's obligations to pay royalties to Regeneron during the Royalty Term pursuant to Article IV. ********** **********.

(d) Tail Period. No later than sixty (60) days prior to the expiration date of this Agreement or the termination of this Agreement by Company pursuant to Section 9.2 (such date being referred to herein as "the Expiration Date"), Company may provide a written notice to Regeneron, which shall be accompanied by a payment of ********** to permit Company to retain and use for a period of one calendar year from the Expiration Date (the "Tail Period") any Mice Materials generated by Company prior to the Expiration Date solely in order to allow Company to ********** prior to the Expiration Date to optimize the development of Antibodies. At the end of such one year Tail Period, Company shall destroy and certify as destroyed all Mice Materials in accordance with the terms in paragraph (c) above.

9.5 Survival. The expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. The second and third sentences of Section 3.1, Section 3.5, Article IV (to the extent applicable, including without limitation, Section 4.2 during the Royalty Term), Section 5.3, Article VI, Section 7.1, Article VIII, subject to Section 8.10, Article IX and Article X, together with any relevant defined terms, shall survive any termination or expiration of this Agreement.

ARTICLE X
MISCELLANEOUS

10.1. Assignment; Successors and Assigns. (a) Company may not assign its rights or delegate its obligations under this Agreement in whole or in part without the prior written consent

of Regeneron, except that Company shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, or (ii) on written notice to Regeneron, to assign all its rights and obligations under this Agreement to any successor in interest in connection with a merger, consolidation or sale of all or substantially all of the assets of Company; provided, that Company's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction. Company absolutely, unconditionally and irrevocably guarantees to Regeneron prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. (b) Regeneron may not assign its rights or delegate its obligations under this Agreement in whole or in part without the prior written consent of Company, except that Regeneron shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, or (ii) on written notice to Company, to assign all its rights and obligations under this Agreement (A) to any of its Affiliates that has the resources to meet Regeneron's obligations under this Agreement, or (B) to a successor in interest in connection with (1) a merger, consolidation or sale of all or substantially all of the assets of Regneron, or (2) the sale or license of all or substantially all of the assets of Regeneron related to the Regeneron Technology; provided that Regeneron's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction. Regeneron absolutely, unconditionally and irrevocably guarantees to Company prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. (c) Any purported assignment in violation of this Section 10.1 shall be void *ab initio*. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act of omission) which such Party is prohibited hereunder from committing directly. No assignment of this Agreement shall be made in bad faith to limit or restrict the contractual rights and benefits of the other Party under this Agreement.

10.2. Notices.

Notices to Company shall be addressed to:

Astellas Pharma Inc.
2-3-11 Nihonbashi-Honcho Chuo-ku
Tokyo 103-8411, Japan
Telefacsimile: **********
Attention: Vice President, Legal

With a copy to: Vice President, Molecular Medicine Research Labs, Drug Discovery Research

Notices to Regeneron shall be addressed to:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6707
USA

Telefacsimile: **********
Attention: Vice President, Strategic Alliances

With a copy to: Vice President & General Counsel

All notices and other correspondence sent under this Agreement shall be in English. Any Party may change its address by giving notice to the other Party in the manner herein provided. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be (a) sent by registered or certified mail, return receipt requested, postage prepaid, (b) sent via a reputable international courier service, (c) sent by facsimile transmission with an original following the same day via a reputable international courier service or (d) personally delivered, in each case properly addressed in accordance with the paragraph above. The effective date of notice shall be the actual date of receipt by the Party receiving the same.

10.3. Governing Law. This Agreement shall be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York notwithstanding any provisions governing conflict of laws under such New York law to the contrary and without giving effect to the United Nations Convention on Contracts for the International Sale of Goods.

10.4. Submission to Jurisdiction. Each Party (a) submits to the exclusive jurisdiction of any state or federal court sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, subject to any rights of removal from state court in New York to federal court in New York, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court; provided that either Party may bring an action in any court of competent jurisdiction to enforce a final judgment entered by such New York courts. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 10.2. Nothing in this Section 10.4, however, shall affect the right of any Party to serve legal process in any other manner permitted by law.

10.5. Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any obligation under this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, pandemic, epidemic, embargoes, war, acts of war (whether war is declared or not), acts of terrorism insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; provided, however, that the Party so affected shall use reasonable commercial efforts to avoid or remove such causes of nonperformance, and shall continue performance hereunder with reasonable dispatch whenever such causes are removed. Each Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of force majeure. The Parties shall mutually seek a resolution of the delay or the failure to perform as noted above.

10.6. Independent Contractors. It is understood and agreed that the relationship between the Parties hereunder is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either Regeneron or Company to act as agent for the other.

10.7. Headings. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.

10.8. Entire Agreement. The Parties acknowledge that this Agreement (together with the confidentiality agreement dated ********** sets forth the entire Agreement and understanding of the Parties as to the subject matter hereof and each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. This Agreement shall not be subject to any change or modification except by the execution of a written instrument subscribed to by the Parties. All other previous or currently existing agreements and understandings or other arrangements of any kind with respect to the said subject matter shall be canceled and superseded completely by this Agreement as of the date hereof. Nothing in this Agreement is intended to limit or exclude any liability for fraud. All Schedules and Exhibits referred to in this Agreement are intended to be and are hereby specifically incorporated into and made part of this Agreement. In the event of any inconsistency between any such Schedules or Exhibits and this Agreement, the terms of this Agreement shall govern.

10.9. No Implied Waivers; Rights Cumulative. No failure on the part of Regeneron or Company to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein. To be effective any waiver must be in writing. No right, power, remedy or privilege herein conferred upon or reserved to a Party is intended to be exclusive of any other right, power, remedy or privilege, and each and every right, power, remedy and privilege of a Party pursuant to this Agreement or now or hereafter existing at law or in equity shall to the extent permitted by law be cumulative, concurrent and in addition to every other right, power, remedy or privilege pursuant to this Agreement or now or hereafter existing at law or in equity.

10.10. Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision of this Agreement invalid or illegal or unenforceable in any respect. To the fullest extent permitted by Applicable Law and if the rights or obligations of any Party will not be materially and adversely affected: (a) such provision will be given no effect by the Parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect, and (c) the Parties shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

10.11. Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the

same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

10.12. Construction. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The term "including" or "includes" as used in this Agreement means including, without limiting the generality of any description preceding such term. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

10.13. No Benefit to Third Parties. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons except as otherwise expressly provided in Section 10.1.

10.14 Limitation of Damages EXCEPT AS PROVIDED BELOW IN THIS SECTION 10.14, IN NO EVENT SHALL REGENERON OR COMPANY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARLDESS OF THE THEORY OF LIABILITY AND REGLARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 10.14 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLGIATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS. MOREOVER, NOTHING IN THIS SECTION 10.14 IS INTENDED TO LIMIT OR RESTRICT ANY LIABILITY FOR FRAUD OR ANY LIABILITY ARISING FROM A BREACH OF SECTION 2.6 OR 5.4.

10.15 Further Assurance. Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration and Chief Financial Officer

ASTELLAS PHARMA INC.

By: /s/ Toshinari Tamura, Ph.D.
Name: Toshinari Tamura, Ph.D.
Title: Representative Director, Executive Vice President and Chief Science Officer

EXHIBIT A

REGENERON KNOW-HOW AND MICE

****

31

EXHIBIT B

REGENERON PATENT RIGHTS

Patent No.:	6,586,251
USSN:	09/732,234
Inventors:	Economides, Murphy, Valenzuela, Yancopoulos
Title:	Methods of Modifying Eukaryotic Cells
Filing Date:	7 Dec 2000
Patent No.:	6,596,541
USSN:	09/784,859
PCT:	2003/6275
Inventors:	Murphy, Yancopoulos
Title:	Methods of Modifying Eukaryotic Cells
Filing Date:	16 Feb 2001 (continuation-in-part of 09/732,234)
Patent No.:	US 7,105,348
USSN:	10/076,840
Inventors:	Murphy, Yancopoulos
Title:	Methods of Modifying Eukaryotic Cells
Filing Date:	15 Feb 2002
780D NZ	Patent No. 527629 Granted 7 July 2005
780D SG	Patent No. 100103 Granted 30 Nov 2005
780D SA	Patent No. 2003/3129 Granted 29 Sept 2005

****

EXHIBIT C

LETTER AGREEMENT WITH APPROVED THIRD PARTIES

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York USA 10591

Ladies and Gentlemen:

In connection with the [ ] agreement (the "Agreement") dated [ ] between [ ] ("Service Provider"), a [ ], with principal offices located at [ ] and [ASTELLAS] ("Astellas"), a [ ] with principal offices located at [ ], Service Provider hereby enters into the following agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron"), a New York corporation, with principal offices located at 777 Old Saw Mill River Road, Tarrytown, New York USA 10591:

1) Service Provider acknowledges that in connection with the Agreement it shall be receiving (i) confidential and proprietary genetically modified mice owned by Regeneron (referred to as "Regeneron Mice"), [(ii) ********** (referred to as "Mice Materials")] and (iii) Regeneron's confidential information related to the breeding of Regeneron Mice and information from breeding Regeneron Mice (referred to as "Regeneron Information").

2) [Service Provider agrees that it shall not use the Regeneron Mice for any purposes other than to breed the Mice solely by means of breeding Regeneron Mice with other Regeneron Mice solely in accordance with the breeding practices supplied by Astellas.] [IF APPLICABLE]

3) Service Provider agrees that Regeneron retains all right, title and interest in the Regeneron Mice and Mice Materials. Without limiting the foregoing, Service Provider hereby assigns to Regeneron any right, title and interest in the Regeneron Mice and Mice Materials. Service Provider agrees to execute any and all further instruments, forms of assignments and other documents, and to take such further actions as Regeneron may request, in order to transfer all of Service Provider's rights, if any, in the Regeneron Mice and Mice Materials to Regeneron without additional consideration.

4) Service Provider agrees that it has no right to use the Regeneron Mice or Mice Materials to discover, develop or otherwise make improvements to the Regeneron Mice or Mice Materials (referred to as "Mice Inventions"). Accordingly, Service Provider shall promptly disclose to Regeneron, in writing, any Mice Inventions and shall, and hereby does, assign, all right, title, and interest it has in Mice Inventions without additional compensation.

5) Service Provider agrees that it: (a) will use diligent efforts to ensure that the Regeneron Mice do not come into contact with any mice other than Regeneron Mice; and, in particular, will not intentionally or recklessly breed Regeneron Mice with any mice

other than Regeneron Mice; (b) will not make any heritable genetic modifications to the Regeneron Mice; (c) will not derive embryonic or other stem cells from the Regeneron Mice or other Mice Material that could be used to make Regeneron Mice; (d) will not use Regeneron Mice or Mice Materials to manufacture or produce products for sale; and (e) will not use Mice Materials to create Regeneron Mice, mice or any transgenic organism.

6) Service Provider agrees to keep Regeneron Information confidential and not disclose to any third party or use for any purpose other than the performance of the Agreement.

7) Service Provider will not distribute or allow the transfer of Regeneron Mice to any third party other than Astellas or its Affiliates and will destroy all Regeneron Mice and Mice Materials in its possession within five (5) business days after notice from Astellas.

8) This letter agreement shall be construed and the rights of the parties hereto shall be determined according to the laws of the State of New York notwithstanding any provisions governing conflict of laws under such New York law to the contrary and without giving effect to the United Nations Convention on Contracts for the International Sale of Goods.

9) This letter agreement may be executed in counterparts, each of which counterpart, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

10) For the avoidance of doubt, it is understood that Regeneron shall not be responsible for Astellas's performance of its obligations under the Agreement and Regeneron shall have no liability or responsibilities under the Agreement.

IN WITNESS WHEREOF, the parties have caused a duly authorized representative to execute this letter agreement as of the date set forth below.

[ ]	REGENERON PHARMACEUTICALS, INC.
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

EXHIBIT D

PRESS RELEASE

ASTELLAS LICENSES REGENERON'S *VELOCIMMUNE*® TECHNOLOGY FOR DISCOVERING HUMAN MONOCLONAL ANTIBODIES

Tokyo, Japan and Tarrytown, NY — (March xx, 2007) — Astellas Pharma Inc. ("Astellas"; Headquarters: Tokyo, Japan; President & CEO: Masafumi Nogimori) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) announced today that they have entered into a non-exclusive license agreement that will allow Astellas to utilize Regeneron's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibody product candidates.

Astellas will pay $20 million upfront and will make up to five additional annual payments of $20 million, subject to the ability to terminate the agreement after making the first three additional payments. Upon commercialization of any antibody products discovered utilizing *VelocImmune*, Astellas will pay a mid-single-digit royalty on product sales. Astellas will report the $80 million license fee for the initial four years as an R&D expense on its income statements for the fiscal year ending March 31, 2007.

"*VelocImmune* is the centerpiece of Regeneron's suite of technologies for the discovery and development of fully human monoclonal antibodies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories and Regeneron's Chief Scientific Officer. "We are pleased that Astellas, a company with a clear strategic commitment to developing therapeutic antibodies, has selected the *VelocImmune* platform for its internal development programs."

"We are excited about this license agreement with Regeneron," said Toshinari Tamura, Ph.D., Astellas' Executive Vice President and Chief Scientific Officer. "As described in our recently announced medium term plan, Astellas is building a new technological platform for the development of antibody drugs, and *VelocImmune* will become an important cornerstone for our R&D capabilities."

VelocImmune

Regeneron's *VelocImmune* technology offers the potential to increase dramatically the speed and efficiency of discovering fully-human, therapeutic monoclonal antibodies. The *VelocImmune* platform generates fully human monoclonal antibodies (hMAbs) to address clinically relevant targets of therapeutic interest. The *VelocImmune* mouse, unlike other hMAb mice, mounts a robust immune response that is virtually indistinguishable from that of a wild type mouse, resulting in a reliable and efficient platform for discovering fully human monoclonal antibodies.

About Astellas Pharma Inc.

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global pharmaceutical company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. For more information on Astellas Pharma Inc., please visit the company's website at http://www.astellas.com.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders.

Regeneron has developed and validated a suite of inter-related technology platforms — *VelociGene*®, *VelociMouse*®, and *VelocImmune* — that the Company believes can increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated. These discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. *VelociGene* uses a proprietary process to create genetic modifications in a mouse in a precise and high-throughput manner and was recently selected by the National Institutes of Health for use in its Knockout Mouse Project. *VelociGene* allows Regeneron to produce mouse embryonic stem (ES) cells rapidly for elucidating the function of the altered genes. *VelociMouse* allows Regeneron scientists to generate mammalian models directly from ES cells without the need for chimeras or breeding. *VelocImmune* provides antibodies that address the targets identified in the mammalian models that can be

developed as potential therapeutics. For more information on Regeneron, please visit the company's website at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2006. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

###

Regeneron Contacts:

Media:
Lauren Tortorete
Tel: 212 845 5609
ltortorete@biosector2.com

Investor Relations:
Charles Poole
Tel: 914 345 7640
charles.poole@regeneron.com

Astellas Contact:
Akihiro Tanaka, Ph.D.
VP, Corporate Communications
Astellas Pharma Inc.
Tel.: +81-3-3244-3201

SCHEDULE 4.2

SAMPLE ROYALTY CALCULATION

****

38

SCHEDULE 5.2

****

39

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Three months ended March 31,
	2002	2003	2004	2005	2006	2007
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	$(124,350)	$(107,395)	$41,565	$(95,456)	$(103,150)	$(29,917)
Fixed charges	13,685	14,108	14,060	13,687	13,643	3,425
Amortization of capitalized interest	—	33	78	78	73	6
Interest capitalized	(222)	(276)	—	—	—	—
Adjusted earnings	$(110,887)	$ (93,530)	$55,703	$(81,691)	$ (89,434)	$(26,486)
Fixed charges:						
Interest expense	$ 11,859	$ 11,932	$12,175	$ 12,046	$ 12,043	$ 3,011
Interest capitalized	222	276	—	—	—	—
Assumed interest component of rental charges	1,604	1,900	1,885	1,641	1,600	414
Total fixed charges	$ 13,685	$ 14,108	$14,060	$ 13,687	$ 13,643	$ 3,425
Ratio of earnings to fixed charges	(A)	(A)	3.96	(A)	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2002, 2003, 2005, and 2006, and for the three months ended March 31, 2007, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Three months ended March 31,
	2002	2003	2005	2006	2007
Coverage deficiency	$124,572	$107,638	$95,378	$103,077	$29,911

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2007

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2007

/s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
May 4, 2007

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
May 4, 2007

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 8/3/2007

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2007

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☑

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of July 31, 2007:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,260,266
Common Stock, $0.001 par value	63,798,205

REGENERON PHARMACEUTICALS, INC.
Table of Contents
June 30, 2007

	Page Numbers
PART I FINANCIAL INFORMATION	
Item 1 Financial Statements	
Condensed balance sheets (unaudited) at June 30, 2007 and December 31, 2006	3
Condensed statements of operations (unaudited) for the three and six months ended June 30, 2007 and 2006	4
Condensed statement of stockholders' equity (unaudited) for the six months ended June 30, 2007	5
Condensed statements of cash flows (unaudited) for the six months ended June 30, 2007 and 2006	6
Notes to condensed financial statements (unaudited)	7-14
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	15-39
Item 3 Quantitative & Qualitative Disclosure About Market Risk	39
Item 4 Controls and Procedures	39-40
PART II OTHER INFORMATION	
Item 1 Legal Proceedings	40
Item 1A Risk Factors	40-57
Item 4 Submission of Matters to a Vote of Security Holders	57
Item 6 Exhibits	58
SIGNATURE PAGE	59
EX-12.1: STATEMENT RE: COMPUTATION OF RATIO OF EARNINGS TO COMBINED FIXED CHARGES	
EX-31.1: CERTIFICATION	
EX-31.2: CERTIFICATION	
EX-32: CERTIFICATION	

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT JUNE 30, 2007 AND DECEMBER 31, 2006 (Unaudited)
(In thousands, except share data)

	June 30, 2007	December 31, 2006
ASSETS		
Current assets		
Cash and cash equivalents	$ 109,643	$ 237,876
Marketable securities	351,054	221,400
Accounts receivable	20,478	7,493
Prepaid expenses and other current assets	15,806	3,215
Total current assets	496,981	469,984
Restricted cash	1,600	1,600
Marketable securities	49,985	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	47,647	49,353
Other assets	1,645	2,170
Total assets	$ 597,858	$ 585,090
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 34,905	$ 21,471
Deferred revenue, current portion	69,926	23,543
Total current liabilities	104,831	45,014
Deferred revenue	113,691	123,452
Notes payable	200,000	200,000
Total liabilities	418,522	368,466
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,270,353 in 2007 and 2006	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 63,783,564 in 2007 and 63,130,962 in 2006	64	63
Additional paid-in capital	924,094	904,407
Accumulated deficit	(744,308)	(687,617)
Accumulated other comprehensive loss	(516)	(231)
Total stockholders' equity	179,336	216,624
Total liabilities and stockholders' equity	$ 597,858	$ 585,090

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
Revenues				
Contract research and development	$ 15,917	$ 14,991	$ 29,562	$ 29,578
Contract manufacturing		4,267		7,899
Technology licensing	6,278		8,421	
	22,195	19,258	37,983	37,477
Expenses				
Research and development	43,864	34,398	85,099	66,482
Contract manufacturing		2,810		4,662
General and administrative	8,935	6,299	17,137	12,245
	52,799	43,507	102,236	83,389
Loss from operations	(30,604)	(24,249)	(64,253)	(45,912)
Other income (expense)				
Investment income	6,841	3,684	13,584	7,165
Interest expense	(3,011)	(3,011)	(6,022)	(6,022)
	3,830	673	7,562	1,143
Net loss before cumulative effect of a change in accounting principle	(26,774)	(23,576)	(56,691)	(44,769)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")				813
Net loss	$ (26,774)	$ (23,576)	$ (56,691)	$ (43,956)
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	$ (0.41)	$ (0.41)	$ (0.86)	$ (0.79)
Cumulative effect of adopting SFAS 123R				0.02
Net loss	$ (0.41)	$ (0.41)	$ (0.86)	$ (0.77)
Weighted average shares outstanding, basic and diluted	65,950	56,915	65,757	56,821

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the six months ended June 30, 2007
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity	Loss
Balance, December 31, 2006	2,270	$ 2	63,131	$ 63	$ 904,407	$ (687,617)	$ (231)	$ 216,624	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			588	1	4,823			4,824	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367			1,367	
Stock-based compensation expense					13,497			13,497	
Net loss						(56,691)		(56,691)	$ (56,691)
Change in net unrealized loss on marketable securities							(285)	(285)	(285)
Balance, June 30, 2007	2,270	$ 2	63,784	$ 64	$ 924,094	$ (744,308)	$ (516)	$ 179,336	$ (56,976)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Six months ended June 30, 2007	2006
Cash flows from operating activities		
Net loss	$ (56,691)	$ (43,956)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	5,729	7,488
Non-cash compensation expense	13,497	8,779
Cumulative effect of a change in accounting principle		(813)
Changes in assets and liabilities		
(Increase) decrease in accounts receivable	(12,985)	24,380
(Increase) decrease in prepaid expenses and other assets	(13,241)	627
Increase in inventory		1,279
Increase (decrease) in deferred revenue	36,622	(8,063)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	14,324	(5,118)
Total adjustments	43,946	28,559
Net cash used in operating activities	(12,745)	(15,397)
Cash flows from investing activities		
Purchases of marketable securities	(371,007)	(152,660)
Sales or maturities of marketable securities	253,719	95,292
Capital expenditures	(3,024)	(986)
Net cash used in investing activities	(120,312)	(58,354)
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	4,824	3,813
Other		390
Net cash provided by financing activities	4,824	4,203
Net decrease in cash and cash equivalents	(128,233)	(69,548)
Cash and cash equivalents at beginning of period	237,876	184,508
Cash and cash equivalents at end of period	$ 109,643	$ 114,960

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2006 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2007 and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended June 30,	
	2007	2006
Net loss (Numerator)	$(26,774)	$(23,576)
Weighted-average shares, in thousands (Denominator)	65,950	56,915
Basic and diluted net loss per share	$ (0.41)	$ (0.41)

	Six Months Ended June 30,	
	2007	2006
Net loss (Numerator)	$(56,691)	$(43,956)
Weighted-average shares, in thousands (Denominator)	65,757	56,821
Basic and diluted net loss per share	$ (0.86)	$ (0.77)

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the June 30, 2007 and 2006 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30,	
	2007	2006
Stock Options:		
Weighted average number, in thousands	15,228	14,181
Weighted average exercise price	$ 15.91	$ 14.32
Restricted Stock:		
Weighted average number, in thousands		40
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

	Six months ended June 30,	
	2007	2006
Stock Options:		
Weighted average number, in thousands	15,388	14,291
Weighted average exercise price	$ 15.78	$ 14.29
Restricted Stock:		
Weighted average number, in thousands		47
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	$ 30.25	$ 30.25

3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2007 and December 31, 2006 are $1.3 million and $0.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at both June 30, 2006 and December 31, 2005 are $0.2 million of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2006 and 2005 are $1.4 million and $1.9 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2007 and 2006, the Company contributed 64,532 and 120,960

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at June 30, 2007 and December 31, 2006 are $2.2 million and $1.5 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2006 and December 31, 2005 are $0.8 million and $1.2 million, respectively, of accrued interest income.

4. Accounts Receivable

Accounts receivable as of June 30, 2007 and December 31, 2006 consist of the following:

	June 30, 2007	December 31, 2006
Receivable from the sanofi-aventis Group	$ 11,410	$ 6,900
Receivable from Bayer HealthCare LLC	7,463	
Other	1,605	593
	$ 20,478	$ 7,493

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2007 and December 31, 2006 consist of the following:

	June 30, 2007	December 31, 2006
Accounts payable	$ 18,546	$ 4,349
Accrued payroll and related costs	7,222	9,932
Accrued clinical trial expense	4,316	2,606
Accrued expenses, other	2,529	2,292
Interest payable on convertible notes	2,292	2,292
	$ 34,905	$ 21,471

6. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and six months ended June 30, 2007 and 2006, the components of comprehensive loss are:

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended June 30,	
	2007	2006
Net loss	$ (26,774)	$ (23,576)
Change in net unrealized gain (loss) on marketable securities	(357)	(102)
Total comprehensive loss	$ (27,131)	$ (23,678)

	Six months ended June 30,	
	2007	2006
Net loss	$ (56,691)	$ (43,956)
Change in net unrealized gain (loss) on marketable securities	(285)	(3)
Total comprehensive loss	$ (56,976)	$ (43,959)

7. Accounting for Collaboration with Bayer HealthCare

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of $75.0 million. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first $50.0 million will be shared equally; Regeneron is solely responsible for the next $40.0 million; over $90.0 million will be shared equally. Through June 30, 2007, reimbursements from Bayer HealthCare of the Company's VEGF Trap-Eye development expenses totaled $10.6 million, of which $7.5 million was receivable at June 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

The Company and Bayer HealthCare are currently formalizing the global development plans for the VEGF Trap-Eye in the collaboration's two initial eye disease indications. The plans will include estimated development steps, timelines and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. Pending completion of these plans, all payments received or receivable by the Company from Bayer HealthCare through June 30, 2007, totaling $85.6 million, have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, the Company will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments (including the $75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development expenses) will be recognized in the Company's Statement of Operations. In the period when the Company commences recognizing previously deferred payments from Bayer HealthCare, the Company anticipates recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

8. 2007 License Agreements

AstraZeneca

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable up-front payment to the Company which was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. AstraZeneca also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's VelocImmune technology. For the six months ended June 30, 2007, the Company recognized $7.1 million of revenue in connection with the AstraZeneca license agreement. At June 30, 2007, deferred revenue was $12.9 million.

Astellas

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable up-front payment to the Company, which was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. Astellas also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. For the six months ended June 30, 2007, the Company recognized $1.3 million of revenue in connection with the Astellas license agreement. At June 30, 2007, deferred revenue was $18.7 million.

9. Commitment — Purchase of Building

In June 2007, the Company exercised a purchase option on a building in Rensselaer, New York, totaling approximately 270,000 square feet, in which the Company currently leases approximately 75,000 square feet of manufacturing, office, and warehouse space. The Company anticipates completing the purchase of this building in the third quarter of 2007 at a cost of approximately $10 million.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

10. Income Taxes

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements.

The Company is primarily subject to U.S. federal and New York State income tax. Tax years subsequent to 1991 remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and June 30, 2007, the Company had no accruals for interest or penalties related to income tax matters.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

12. Segment Information

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to activities conducted under contract research and technology licensing agreements.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006, the Company produced a vaccine intermediate for Merck & Co., Inc. under a manufacturing agreement, which expired in October 2006.

Due to the expiration of the Company's manufacturing agreement with Merck in October 2006, beginning in 2007, the Company only has a research and development business segment. Therefore, segment information has not been provided for 2007 in the table below.

The following table presents information about reported segments for the three and six months ended June 30, 2006.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended June 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 14,991	$4,267	—	$ 19,258
Depreciation and amortization	3,429	— (1)	$ 261	3,690
Non-cash compensation expense	4,603	97	—	4,700
Interest expense	—	—	3,011	3,011
Net (loss) income	(25,706)	1,457	673 (2)	(23,576)
Capital expenditures	323	—	—	323

	Six months ended June 30, 2006			
	Research & Development	Contract Manufacturing	Reconciling Items	Total
Revenues	$ 29,578	$7,899	—	$ 37,477
Depreciation and amortization	6,966	— (1)	$ 522	7,488
Non-cash compensation expense	8,587	192	(813)(4)	7,966
Interest expense	—	—	6,022	6,022
Net (loss) income	(49,149)	3,237	1,956 (2)	(43,956)
Capital expenditures	968	—	—	968
Total assets	64,543	3,580	310,209 (3)	378,332

(1) Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

(2) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the six months ended June 30, 2006, also includes the cumulative effect of adopting Statement of Financial Accounting Standards No. ("SFAS") 123R, *Share-Based Payment*.

(3) Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

(4) Represents the cumulative effect of adopting SFAS 123R.

13. Future Impact of Recently Issued Accounting Standards

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company will be required to adopt SFAS 159 effective

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)
(Unless otherwise noted, dollars in thousands, except per share data)

for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 159 on the Company's financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company will be required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Management believes that the future adoption of EITF 07-3 will not have a material impact on the Company's financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: rilonacept (IL-1 Trap) in various inflammatory indications, the VEGF Trap (aflibercept) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the VelocImmune platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move our first new antibody product candidate into clinical trials in the fourth quarter of 2007. We plan to introduce two new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the status of our clinical candidates as of June 30, 2007:

1. Rilonacept — Inflammatory Diseases

Rilonacept (IL-1 Trap) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating rilonacept in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

We recently submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for rilonacept in CAPS. The FDA has previously granted Orphan Drug status and Fast Track designation to rilonacept for the treatment of CAPS. In July 2007, rilonacept also received Orphan Drug designation in the European Union for the treatment of CAPS.

In October 2006, we announced positive data from our Phase 3 clinical trial, which was designed to provide two separate demonstrations of efficacy for rilonacept within a single group of adult patients suffering from CAPS. This Phase 3 trial included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: $p < 0.0001$ and Part B: $p < 0.001$). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive rilonacept had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ($p<0.0001$). Following a 9-week interval during which all patients received rilonacept, a "randomized withdrawal" study (Part B) was performed, in which the patients in Part A were re-randomized to either switch to placebo or continue treatment with rilonacept in a double-blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on rilonacept who had no significant change ($p<0.001$). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on rilonacept than on placebo. In these studies, rilonacept appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. See Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates."

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of rilonacept in other indications in which IL-1 may play a role. We are completing an exploratory proof of concept study of rilonacept in ten patients with chronic gout, and plan to begin a safety and efficacy study of rilonacept in gout patients in the third quarter of 2007. We are also preparing to initiate exploratory proof of concept studies of rilonacept in other indications, the first of which is planned to begin in the fourth quarter of 2007.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation rilonacept following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our rilonacept currently in clinical development.

2. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap (aflibercept) is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are preparing to initiate a large Phase 3 program that will evaluate the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in five different cancer types. The first trial is planned to begin in the third quarter of 2007. The Phase 3 trials are planned in the following indications:

- first-line metastatic hormone resistant prostate cancer in combination with Taxotere®(Aventis),
- first-line metastatic pancreatic cancer in combination with gemcitabine-based regimen,
- first-line gastric cancer in combination with Taxotere® (Aventis),
- second-line non-small cell lung cancer in combination with Taxotere® (Aventis), and
- second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan).

Currently, the collaboration is conducting Phase 2 single-agent studies in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the FDA granted Fast Track designation to the VEGF Trap for the treatment of SMA.

In June 2007, at the annual meeting of the American Society of Clinical Oncology (ASCO), we and sanofi-aventis announced interim results from the Phase 2 studies in AOC and NSCLA. The AOC study, selected for an oral presentation at ASCO, was an interim analysis of a Phase 2 randomized, double-blind, multi-center trial investigating two doses of the VEGF Trap used as a single agent in patients with recurrent platinum-resistant epithelial ovarian cancer. While the study remains blinded with regard to dose, the combined preliminary results of the two dose levels for 162 of a planned 200 patients demonstrated anti-tumor activity as evidenced by an 8.0% partial response rate and 77% achievement of stable disease at 4 weeks in heavily pre-treated patients who had failed multiple other treatments. The VEGF Trap has been well tolerated, and the most common adverse events have been the typical class effect of anti-angiogenic agents. Of the 23 patients in the AOC study with evaluable baseline ascites, 7 patients (30%) experienced complete disappearance of the ascites, and 13 patients (57%) experienced no increase in ascites during treatment. The AOC study is ongoing and is now fully enrolled.

The NSCLA study, presented as a poster at ASCO, is a Phase 2 single-arm study conducted in patients with platinum-resistant and erlotinib-resistant adenocarcinoma of the lung (a common type of non-small cell lung cancer). In this study, the preliminary results presented at ASCO demonstrated activity in this heavily pre-treated patient base, as evidenced by a 3.7% partial response rate and 63% of patients achieving stable disease. The VEGF Trap has been well-tolerated in this trial as well. This study is ongoing and is now fully enrolled.

Sanofi-aventis has indicated that a first registration submission to a regulatory agency for the VEGF Trap is possible as early as 2008.

In addition, eight clinical studies have begun in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP). We and sanofi-aventis are working to finalize plans with NCI/CTEP to conduct additional trials in different cancer types.

Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the planned Phase 3 clinical program. In addition, sanofi-aventis has initiated the first trial of the VEGF Trap in

Japan, a Phase 1 safety and tolerability study in combination with S-1 in patients with advanced solid malignancies.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (Genentech) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to $400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to $360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another $40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In the clinical development program for the VEGF Trap-Eye, we and Bayer HealthCare announced that we have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial will compare the VEGF Trap-Eye and Genentech, Inc.'s Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. This Phase 3 trial is evaluating dosing intervals of four and eight weeks for the VEGF Trap-Eye compared with ranibizumab dosing according to its label every four weeks. Regeneron and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD around the end of 2007.

In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), we and Bayer HealthCare reported positive interim data from a pre-planned interim analysis of the Phase 2 study in wet AMD. The Phase 2 trial is a 150 patient, 12 week, study that is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. In the interim data analysis, the VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns, $p < 0.0001$). Mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters, $p < 0.0001$). Moreover, patients in the dose groups that received only a single dose, on average, compared to baseline, demonstrated a decrease in excess retinal thickness ($p < 0.0001$) and an increase in visual acuity ($p = 0.012$) at 12 weeks. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. Detailed data from this interim analysis is scheduled for presentation at an upcoming scientific conference. All patients have now completed 12 weeks of treatment, and we and Bayer HealthCare expect to report the results at a scientific conference in the third quarter of 2007. We are also conducting a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in wet AMD.

We are also developing the VEGF Trap-Eye in DME. In May 2007, at the ARVO meeting, the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity. We expect to initiate a safety and efficacy study in DME in the second half of 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and

Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare and can earn up to $110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135.0 million in sales milestones if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200.0 million.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2007, we had a cumulative loss of $744.3 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur

substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and rilonacept; advance new product candidates into clinical development from our existing research programs utilizing our technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2007 and plans over the next 12 months are as follows:

Clinical Program	2007 Events to Date	2007-8 Plans
VEGF Trap - Oncology	• NCI/CTEP initiated eight Phase 2 studies of the VEGF Trap as a single agent • Reported interim results from two Phase 2 single-agent trials - - in advanced ovarian cancer and in non-small cell lung adenocarcinoma • Initiated Japanese Phase 1 trial of VEGF Trap in combination with S-1 in patients with solid malignancies	• Sanofi-aventis to initiate three of five Phase 3 studies of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer indications • NCI/CTEP to initiate additional new exploratory safety and efficacy studies
VEGF Trap-Eye (intravitreal injection)	• Reported positive interim results of Phase 2 trial in wet AMD • Reported positive results in Phase 1 trial in DME • Initiated first Phase 3 trial in wet AMD	• Report final results of Phase 2 trial in wet AMD • Initiate second Phase 3 trial in wet AMD • Initiate safety and efficacy trial in DME • Explore additional eye disease indications

Clinical Program	2007 Events to Date	2007-8 Plans
Rilonacept (IL-1 Trap)	• Completed the 24 week open-label safety extension phase of the Phase 3 trial in CAPS • Submitted BLA to the FDA for CAPS • Orphan Drug designation in CAPS granted in European Union	• FDA acceptance of BLA submission for CAPS and establishment of target completion date for FDA review of BLA • Report results of exploratory proof of concept study in patients with chronic gout • Initiate safety and efficacy trial in gout • Evaluate rilonacept in other disease indications in which IL-1 may play an important role
VelocImmune®		• Initiate first trial for antibody product candidate • Finalize plans to initiate clinical trials for two additional antibody candidates in 2008

License Agreements

AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million non-refundable up-front payment to us. AstraZeneca also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune technology.

Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million non-refundable up-front payment to us. Astellas also will make up to five additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune technology.

Accounting for Collaboration with Bayer HealthCare

As described above, in October 2006 we entered into a VEGF Trap-Eye license and collaboration agreement with Bayer HealthCare. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of $75.0 million. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first $50.0 million will be shared equally;

Regeneron is solely responsible for the next $40.0 million; over $90.0 million will be shared equally. Through June 30, 2007, reimbursements from Bayer HealthCare of our VEGF Trap-Eye development expenses total $10.6 million, of which $7.5 million was receivable at June 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

We and Bayer HealthCare are currently formalizing our global development plans for the VEGF Trap-Eye in wet AMD and DME. The plans will include estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. Pending completion of these plans, all payments received or receivable from Bayer HealthCare through June 30, 2007, totaling $85.6 million, have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, we will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments from Bayer (including the $75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development expenses) will be recognized in our Statement of Operations. In the period when we commence recognizing previously deferred payments from Bayer HealthCare, we anticipate recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

Results of Operations

Three Months Ended June 30, 2007 and 2006

Net Loss:

Regeneron reported a net loss of $26.8 million, or $0.41 per share (basic and diluted), for the second quarter of 2007 compared to a net loss of $23.6 million, or $0.41 per share (basic and diluted), for the second quarter of 2006.

Revenues:

Revenues for the three months ended June 30, 2007 and 2006 consist of the following:

(In millions)	2007	2006	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 13.5	$ 14.8	$ (1.3)
Other	2.4	0.2	2.2
Total contract research & development revenue	15.9	15.0	0.9
Contract manufacturing revenue		4.3	(4.3)
Technology licensing revenue	6.3		6.3
Total revenue	$ 22.2	$ 19.3	$ 2.9

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of

reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue
(In millions)

	Three months ended June 30, 2007	2006
Regeneron expense reimbursement	$ 11.3	$ 11.8
Recognition of deferred revenue related to up-front payments	2.2	3.0
Total	$ 13.5	$ 14.8

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the second quarter of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the second quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of June 30, 2007, $65.5 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes $1.6 million recognized in connection with our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the second quarter of 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 was $0.4 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the $20.0 million non-refundable up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the $20.0 million non-refundable up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. In the second quarter of 2007, we recognized $6.3 million of technology licensing revenue related to these agreements.

Expenses:

Total operating expenses increased to $52.8 million in the second quarter of 2007 from $43.5 million in the same period of 2006. Our average employee headcount in the second quarter of

2007 increased to 618 from 579 in the second quarter of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials later this year. Operating expenses in the second quarter of 2007 and 2006 include a total of $6.9 million and $4.6 million, respectively, of non-cash compensation expense related to employee stock option awards (Stock Option Expense), as detailed below:

(In millions)	For the three months ended June 30, 2007		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 39.9	$ 4.0	$ 43.9
General and administrative	6.0	2.9	8.9
Total operating expenses	$ 45.9	$ 6.9	$ 52.8

(In millions)	For the three months ended June 30, 2006		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 31.8	$ 2.6	$ 34.4
Contract manufacturing	2.7	0.1	2.8
General and administrative	4.4	1.9	6.3
Total operating expenses	$ 38.9	$ 4.6	$ 43.5

The increase in total Stock Option Expense in the second quarter of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to $43.9 million in the second quarter of 2007 from $34.4 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2007 and 2006:

(In millions)	Three months ended June 30,		
Research and development expenses	**2007**	**2006**	**Increase**
Payroll and benefits (1)	$ 14.4	$ 11.7	$ 2.7
Clinical trial expenses	6.5	4.4	2.1
Clinical manufacturing costs (2)	11.5	9.1	2.4
Research and preclinical development costs	6.1	4.3	1.8
Occupancy and other operating costs	5.4	4.9	0.5
Total research and development	$ 43.9	$ 34.4	$ 9.5

(1) Includes $3.3 million and $2.2 million of Stock Option Expense for the three months ended June 30, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million and $0.4 million of Stock Option Expense for the three months ended June 30, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to the increase in employee headcount, as described above, and annual salary increases effective January 1, 2007. Clinical trial expenses increased due primarily to (i) higher costs related to our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD, (ii) start-up costs related to our upcoming Phase 3 study of the VEGF Trap-Eye in wet AMD, and (iii) higher rilonacept costs. Clinical manufacturing costs increased primarily because capacity which had previously been dedicated to manufacture of a vaccine intermediate for Merck, and whose cost had been included with Contract Manufacturing Expenses in 2006, has now been designated for, and the related costs included in, clinical manufacturing. In addition, higher costs related to manufacturing rilonacept and preclinical and clinical supplies of our first antibody drug candidate were partly offset by lower costs related to manufacturing VEGF Trap. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs. In addition, higher preclinical development costs related to VEGF Trap and VEGF Trap-Eye were partly offset by lower preclinical development costs related to rilonacept.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

(In millions)	Three months ended June 30,		
Project Costs	**2007**	**2006**	**Increase (Decrease)**
VEGF Trap — Oncology	$ 10.0	$ 10.1	$ (0.1)
VEGF Trap- Eye	8.4	4.1	4.3
Rilonacept	8.1	7.4	0.7
Other research programs & unallocated costs	17.4	12.8	4.6
Total research and development expenses	$ 43.9	$ 34.4	$ 9.5

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical

programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of rilonacept, VEGF Trap, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described below in Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows. We submitted a BLA for our rilonacept for the treatment of CAPS, a spectrum of rare genetic disorders, in the second quarter of 2007. We cannot predict whether or when the commercialization of rilonacept in CAPS will result in a material net cash inflow to the company.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased in the second quarter of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to $8.9 million in the second quarter of 2007 from $6.3 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense due, in part, to increases in administrative headcount in 2007 to support our expanded research and development activities and annual salary increases effective January 1, 2007, (iii) higher recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) marketing research and related expenses incurred in 2007 in connection with our rilonacept and VEGF Trap-Eye programs.

Other Income and Expense:

Investment income increased to $6.8 million in the second quarter of 2007 from $3.7 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was $3.0 million in the second quarter of 2007 and 2006. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Six Months Ended June 30, 2007 and 2006

Net Loss:

Regeneron reported a net loss of $56.7 million, or $0.86 per share (basic and diluted), for the first half of 2007 compared to a net loss of $44.0 million, or $0.77 per share (basic and diluted), for the same period of 2006.

Revenues:

Revenues for the six months ended June 30, 2007 and 2006 consist of the following:

(In millions)	2007	2006	Increase (Decrease)
Contract research & development revenue			
The sanofi-aventis Group	$ 25.3	$ 28.7	$ (3.4)
Other	4.3	0.9	3.4
Total contract research & development revenue	29.6	29.6	—
Contract manufacturing revenue		7.9	(7.9)
Technology licensing revenue	8.4		8.4
Total revenue	$ 38.0	$ 37.5	$ 0.5

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with SAB 104 and EITF 00-21. We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of $105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Six months ended June 30, 2007	2006
Regeneron expense reimbursement	$ 20.8	$ 22.6
Recognition of deferred revenue related to up-front payments	4.5	6.1
Total	$ 25.3	$ 28.7

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the first half of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the first quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of June 30, 2007, $65.5 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes $2.3 million recognized in the first half of 2007 related to our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the first six months of 2006 related to our long-term manufacturing agreement with Merck, which expired in October 2006. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 was $0.8 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the $20.0 million non-refundable up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the $20.0 million non-refundable up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. In the first six months of 2007, we recognized $8.4 million of technology licensing revenue related to these agreements.

Expenses:

Total operating expenses increased to $102.2 million in the first half of 2007 from $83.4 million in the same period of 2006. Our average employee headcount in the first half of 2007 increased to 602 from 583 in the first half of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials later this year. Operating expenses for the first six months of 2007 and 2006 include a total of $13.5 million and $8.5 million, respectively, of Stock Option Expense, as detailed below:

(In millions)	**For the six months ended June 30, 2007**		
Expenses	**Expenses before inclusion of Stock Option Expense**	**Stock Option Expense**	**Expenses as Reported**
Research and development	$ 77.2	$ 7.9	$ 85.1
General and administrative	11.5	5.6	17.1
Total operating expenses	$ 88.7	$ 13.5	$ 102.2

(In millions)	For the six months ended June 30, 2006		
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option Expense	Expenses as Reported
Research and development	$ 61.9	$ 4.6	$ 66.5
Contract manufacturing	4.5	0.2	4.7
General and administrative	8.5	3.7	12.2
Total operating expenses	$ 74.9	$ 8.5	$ 83.4

The increase in total Stock Option Expense in the first half of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to $85.1 million in the first half of 2007 from $66.5 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2007 and 2006:

(In millions)	Six months ended June 30,		
Research and development expenses	2007	2006	Increase
Payroll and benefits (1)	$ 28.1	$ 21.7	$ 6.4
Clinical trial expenses	11.8	7.8	4.0
Clinical manufacturing costs (2)	22.0	18.4	3.6
Research and preclinical development costs	12.1	7.8	4.3
Occupancy and other operating costs	11.1	10.8	0.3
Total research and development	$ 85.1	$ 66.5	$ 18.6

(1) Includes $6.4 million and $3.8 million of Stock Option Expense for the six months ended June 30, 2007 and 2006, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.5 million and $0.8 million of Stock Option Expense for the six months ended June 30, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to the increase in employee headcount, as described above, and annual salary increases effective January 1, 2007. Clinical trial expenses increased due primarily to (i) higher costs related to our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD, (ii) start-up costs related to our upcoming Phase 3 study of the VEGF Trap-Eye in wet AMD, and (iii) higher rilonacept costs. Clinical manufacturing costs increased primarily because capacity which had previously been dedicated to manufacture of a vaccine intermediate for Merck, and whose cost had been included with Contract Manufacturing Expenses in 2006, has now been designated for, and the related costs included in, clinical manufacturing. Higher costs related to manufacturing rilonacept and preclinical and clinical supplies of our first antibody drug candidate were offset by lower costs related to manufacturing VEGF Trap. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs. In addition, higher preclinical development

costs related to VEGF Trap-Eye and VEGF Trap-Oncology were partly offset by lower preclinical development costs related to rilonacept.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

(In millions)	Six months ended June 30,		
Project Costs	**2007**	**2006**	**Increase (Decrease)**
VEGF Trap — Oncology	$ 17.8	$ 19.2	$ (1.4)
VEGF Trap- Eye	14.2	7.8	6.4
Rilonacept	15.9	14.3	1.6
Other research programs & unallocated costs	37.2	25.2	12.0
Total research and development expenses	$ 85.1	$ 66.5	$ 18.6

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2007 and 2006, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased in the first half of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to $17.1 million in the first half of 2007 from $12.2 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense due, in part, to increases in administrative headcount in 2007 to support our expanded research and development activities and annual salary increases effective January 1, 2007, (iii) higher recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) marketing research and related expenses incurred in 2007 in connection with our rilonacept and VEGF Trap-Eye programs.

Other Income and Expense:

Investment income increased to $13.6 million in the first half of 2007 from $7.2 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities

(due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was $6.0 million in first half of 2007 and 2006. Interest expense is attributable primarily to $200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, payments earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

Six Months Ended June 30, 2007 and 2006

At June 30, 2007, we had $512.3 million in cash, cash equivalents, restricted cash, and marketable securities, compared with $522.9 million at December 31, 2006. In connection with our new non-exclusive license agreements with AstraZeneca and Astellas, as described above, AstraZeneca and Astellas each made an up-front payment to us of $20.0 million in February and April 2007, respectively.

Cash (Used in) Operations:

Net cash used in operations was $12.7 million in the first six months of 2007, compared to $15.4 million in the first six months of 2006. Our net losses of $56.7 million in the first half of 2007 and $44.0 million in the first half of 2006 included $13.5 million and $8.8 million, respectively, of non-cash stock-based employee compensation costs, of which $13.5 million and $8.5 million, respectively, represented Stock Option Expense and, in the first half of 2006, $0.3 million represented non-cash compensation expense from Restricted Stock awards. At June 30, 2007, accounts receivable balances increased by $13.0 million, compared to year end 2006, primarily due to amounts receivable from sanofi-aventis and Bayer HealthCare for reimbursements of our VEGF Trap-Oncology and VEGF Trap-Eye development costs, respectively. Also, our deferred revenue balances at June 30, 2007 increased by $36.6 million, compared to year end 2006, primarily due to the $20.0 million up-front payments received from each of AstraZeneca and Astellas, as described above. In addition, for the first six months of 2007, reimbursements from Bayer HealthCare of our 2007 VEGF Trap-Eye development expenses, totaling $10.6 million, have been fully deferred and included in deferred revenue for financial statement purposes, as discussed above. At June 30, 2006, accounts receivable balances decreased by $24.4 million, compared to year end 2005, primarily due to the January 2006 receipt of a $25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our collaboration agreement to include Japan. Also, our deferred revenue balances at June 30, 2006 decreased by $8.1 million, compared to year end 2005, due primarily to first half 2006 revenue recognition of $6.1 million of deferred revenue related to up-front payments from sanofi-aventis. The majority of our cash expenditures in both the first half of 2007 and 2006 were to fund research and development, primarily related to our clinical programs and, in the first half of 2007, our preclinical human monoclonal antibody programs.

Cash Used in Investing Activities:

Net cash used in investing activities was $120.3 million in the first half of 2007 compared to $58.4 million in the same period of 2006, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first half of 2007, purchases of marketable securities exceeded sales or maturities by $117.3 million, whereas in the first half of 2006, purchases of marketable securities exceeded sales or maturities by $57.4 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to $4.8 million in the first half of 2007 from $4.2 million in the same period in 2006 due primarily to an increase in the issuance of Common Stock in connection with exercises of employee stock options.

License Agreements with AstraZeneca and Astellas:

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a $20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas also will each make up to five additional annual payments of $20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $3.5 million and $1.0 million for the first half of 2007 and 2006, respectively. During the remainder of 2007, we expect to incur approximately $13 million in capital expenditures primarily to support our manufacturing, development, and research activities.

During the second quarter of 2007, we exercised a purchase option on a building in Rensselaer, totaling approximately 270,000 square feet, in which we currently lease approximately 75,000 square feet of manufacturing, office and warehouse space. The acquisition of the building and related costs are expected to approximate $10 million, which is included in our anticipated capital expenditures for the remainder of 2007, as described above. We expect to complete the purchase of this building in the third quarter of 2007. The space that we do not occupy in this building is currently leased to another tenant.

Convertible Debt:

In 2001, we issued $200.0 million aggregate principal amount of convertible senior subordinated notes, which bear interest at 5.5% per annum, payable semi-annually, and mature in October 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately $30.25 per share, subject to adjustment in certain circumstances. If the price per share of our Common Stock is above $30.25 at maturity, we would expect the notes to convert into shares of Common Stock. Otherwise, we will be required to repay the $200.0

million aggregate principal amount of the notes or refinance the notes prior to maturity; however, we can provide no assurance that we will be able to successfully arrange such refinancing.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2007 will be directed toward the preclinical and clinical development of product candidates, including rilonacept, VEGF Trap, VEGF Trap-Eye and monoclonal antibodies; approximately 10%-15% of our expenditures for 2007 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2007 will be used for capital expenditures and general corporate purposes.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare are sharing agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as follows:

2007: Up to $50.0 million shared equally; we are solely responsible for up to the next $40.0 million; over $90.0 million shared equally.

2008: Up to $70.0 million shared equally, we are solely responsible for up to the next $30.0 million; over $100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

In addition, under our collaboration agreements with sanofi-aventis and Bayer Healthcare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer Healthcare for 50% of agreed-upon development expenses incurred by sanofi-aventis and Bayer Healthcare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of the VEGF Trap-Oncology in collaboration with sanofi-aventis and the VEGF Trap-Eye in collaboration with Bayer Healthcare) such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer Healthcare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies,

laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the $200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. Other than the $1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

Revenue Recognition:

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of

each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period. Payments for development activities where Regeneron is not sharing costs are recognized as revenue as earned, over the period of effort. In addition, we record revenue in connection with a government research grant as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if we and our collaborators decide to expand our clinical plans for a drug candidate into additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front payment at the time of the termination. For the year ended December 31, 2006, changes in estimates of our performance periods, including an extension of our estimated performance period for our collaboration with sanofi-aventis, did not have a material impact on contract research and development revenue that we recognized. In 2007, we currently expect to recognize at least $2.4 million lower contract research and development revenue, compared to amounts recognized in 2006, in connection with $105.0 million of non-refundable up-front payments previously received from sanofi-aventis, due to an extension of our estimated performance period.

As described above, we and Bayer HealthCare are currently formalizing our global development plans for the VEGF Trap-Eye in wet AMD and DME. Pending completion of these plans, all payments received or receivable from Bayer HealthCare through June 30, 2007 have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, we will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments from Bayer (including the $75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development

expenses) will be recognized in our Statement of Operations. In the period when we commence recognizing previously deferred payments from Bayer HealthCare, we anticipate recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

Clinical Trial Expenses:

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those with a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the year ended December 31, 2006 or the six months ended June 30, 2007.

During the three months ended June 30, 2007, there were no changes to any other "Critical Accounting Policies and Significant Judgments and Estimates" described in our Annual Report on Form 10-K for the year ended December 31, 2006.

Future Impact of Recently Issued Accounting Standards

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. (SFAS) 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 159 on our financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We will be required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Our management believes that the future adoption of EITF 07-3 will not have a material impact on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a $2.0 million and $0.9 million change in the fair market value of our investment portfolio at June 30, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at June 30, 2007, compared to June 30, 2006, is due primarily to increases in our investment portfolio's balance and duration at the end of June 2007 versus June 2006.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the

end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2006 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2007, we had a cumulative loss of $744.3 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the $200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than

tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and rilonacept, in a wide variety of indications. We are studying the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and rilonacept in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of rilonacept in different diseases after a Phase 2 trial using lower doses of rilonacept in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the Phase 3 clinical program for rilonacept in CAPS (Cryopyrin Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of rilonacept.

We recently submitted a BLA to the FDA for rilonacept in CAPS. However, the efficacy and safety data from the Phase 3 clinical program included in the BLA may be inadequate to support approval for commercialization of rilonacept. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for rilonacept, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize rilonacept profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of rilonacept in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test rilonacept in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), rilonacept affects the immune defense system of the body by blocking some of its functions. Therefore, rilonacept may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking rilonacept. One subject with adult Still's diseases in a study of rilonacept developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymayalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of rilonacept in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of rilonacept have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of rilonacept.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date — in some cases even after pivotal clinical trials have been completed. Of the clinical study subjects who received rilonacept for rheumatoid arthritis and other

indications, fewer than 5% of patients developed antibodies and no side effects related to antibodies were observed. Using a very sensitive test, approximately 40% of the patients in the CAPS pivotal study tested positive at least once for low levels of antibodies to rilonacept. Again, no side effects related to antibodies were observed and there were no observed effects on drug efficacy or drug levels. However, it is possible that as we continue to test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and rilonacept, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our VelocImmune technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval

from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2006, which report was included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to

develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience

additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain

these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions,

form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis® (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Biotechnology Ltd.), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize rilonacept. This is one of the reasons we discontinued

the development of rilonacept in adult rheumatoid arthritis. In addition, even if rilonacept is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over rilonacept, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. It has been reported that Novartis has commenced advanced clinical testing of its IL-1 antibody in Muckle-Wells Syndrome, which is part of the spectrum of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over rilonacept. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize rilonacept. For example, we may find it difficult to enroll patients in clinical trials for rilonacept if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing rilonacept for the treatment of a spectrum of rare diseases associated with mutations in the *CIAS*1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize rilonacept in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We are seeking approval to market rilonacept for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize rilonacept. Physicians may not prescribe rilonacept and CAPS patients may not be able to afford rilonacept if third party payers do not agree to reimburse the cost of rilonacept therapy and this would adversely affect our ability to commercialize rilonacept profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our

products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including rilonacept, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 12, 2007, our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. As of April 12, 2007, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 4.4% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 12, 2007, holders of Class A Stock held 26.4% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly

influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 12, 2007:

- our current executive officers and directors beneficially owned 13.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007, and 30.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007; and
- our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. In addition, these seven shareholders held 51.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 12, 2007.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect

of which is to require that shareholder action may only be taken at a duly convened meeting;

- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Item 4. Submission of Matters to a Vote of Security Holders

On June 8, 2007, we conducted our Annual Meeting of Shareholders pursuant to due notice. A quorum being present either in person or by proxy, the shareholders voted on the following matters:

1. To elect three Directors to hold office for a three-year term as Class I directors, and until their successors are duly elected and qualified.

2. To ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for our fiscal year ending December 31, 2007.

No other matters were voted on. The number of votes cast was:

	For	Withheld
1. Election of Class I Directors		
Leonard S. Schleifer, M.D., Ph.D.	78,309,187	1,546,154
Eric M. Shooter, Ph.D.	78,754,194	1,110,147
George D. Yancopoulos, M.D., Ph.D.	78,751,885	1,103,456

The terms of office of Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., P. Roy Vagelos, M.D., Charles A. Baker, Michael S. Brown, M.D., Arthur F. Ryan, and George L. Sing continued after the meeting.

	For	Against	Abstain
2. Ratification of the Appointment of Independent Registered Public Accounting Firm	79,244,209	217,182	393,949

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	- Statement re: computation of ratio of earnings to combined fixed charges.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: August 3, 2007

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Exhibit 12.1

Regeneron Pharmaceuticals, Inc.
Computation of Ratio of Earnings to Combined Fixed Charges
(Dollars in thousands)

	Years ended December 31,					Six months ended June 30,
	2002	2003	2004	2005	2006	2007
Earnings:						
Income (loss) from continuing operations before income (loss) from equity investee	$(124,350)	$(107,395)	$41,565	$(95,456)	$(103,150)	$(56,691)
Fixed charges	13,685	14,108	14,060	13,687	13,643	6,854
Amortization of capitalized interest	—	33	78	78	73	12
Interest capitalized	(222)	(276)	—	—	—	—
Adjusted earnings	$(110,887)	$ (93,530)	$55,703	$(81,691)	$ (89,434)	$(49,825)
Fixed charges:						
Interest expense	$ 11,859	$ 11,932	$12,175	$ 12,046	$ 12,043	$ 6,022
Interest capitalized	222	276	—	—	—	—
Assumed interest component of rental charges	1,604	1,900	1,885	1,641	1,600	832
Total fixed charges	$ 13,685	$ 14,108	$14,060	$ 13,687	$ 13,643	$ 6,854
Ratio of earnings to fixed charges	(A)	(A)	3.96	(A)	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2002, 2003, 2005, and 2006, and for the six months ended June 30, 2007, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	Years ended December 31,				Six months ended June 30,
	2002	2003	2005	2006	2007
Coverage deficiency	$124,572	$107,638	$95,378	$103,077	$56,679

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2007

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2007

/s/ Murray A. Goldberg
Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
August 3, 2007

/s/ Murray A. Goldberg

Murray A. Goldberg
Chief Financial Officer
August 3, 2007

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 4/30/2009

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2009

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No __

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes __ No __

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer __

Non-accelerated filer ___ (Do not check if a smaller reporting company) Smaller reporting company __

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes __ No X

Number of shares outstanding of each of the registrant's classes of common stock as of April 14, 2009:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,246,698
Common Stock, $0.001 par value	77,845,431

REGENERON PHARMACEUTICALS, INC.
Table of Contents
March 31, 2009

		Page Numbers
PART I.	FINANCIAL INFORMATION	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at March 31, 2009 and December 31, 2008	3
	Condensed statements of operations (unaudited) for the three months ended March 31, 2009 and 2008	4
	Condensed statement of stockholders' equity (unaudited) for the three months ended March 31, 2009	5
	Condensed statements of cash flows (unaudited) for the three months ended March 31, 2009 and 2008	6
	Notes to condensed financial statements (unaudited)	7-10
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	11-28
Item 3	Quantitative and Qualitative Disclosures About Market Risk	29
Item 4	Controls and Procedures	29
PART II	OTHER INFORMATION	
Item 1	Legal Proceedings	29
Item 1A	Risk Factors	29-44
Item 6	Exhibits	44
SIGNATURE PAGE		45

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT MARCH 31, 2009 AND DECEMBER 31, 2008 (Unaudited)
(In thousands, except share data)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	$ 199,097	$ 247,786
Marketable securities	216,785	226,954
Accounts receivable from the sanofi-aventis Group	44,676	33,302
Accounts receivable - other	3,633	1,910
Prepaid expenses and other current assets	19,700	11,490
Total current assets	483,791	521,442
Restricted cash	1,650	1,650
Marketable securities	78,460	51,061
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	109,840	87,853
Other assets	7,680	8,032
Total assets	$ 681,421	$ 670,038
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 44,832	$ 36,168
Deferred revenue from sanofi-aventis, current portion	21,525	21,390
Deferred revenue - other, current portion	36,756	26,114
Total current liabilities	103,113	83,672
Deferred revenue from sanofi-aventis	100,474	105,586
Deferred revenue - other	54,364	56,835
Other long term liabilities	13,150	5,093
Total liabilities	271,101	251,186
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,246,698 in 2009 and 2,248,698 in 2008	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 77,841,540 in 2009 and 77,642,203 in 2008	78	78
Additional paid-in capital	1,304,896	1,294,813
Accumulated deficit	(893,408)	(875,927)
Accumulated other comprehensive loss	(1,248)	(114)
Total stockholders' equity	410,320	418,852
Total liabilities and stockholders' equity	$ 681,421	$ 670,038

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended March 31,	
	2009	2008
Revenues		
Contract research and development from sanofi-aventis	$ 49,660	$ 35,734
Other contract research and development	11,430	10,649
Technology licensing	10,000	10,000
Net product sales	3,891	
	74,981	56,383
Expenses		
Research and development	82,146	61,270
Selling, general, and administrative	11,674	11,024
Cost of goods sold	392	
	94,212	72,294
Loss from operations	(19,231)	(15,911)
Other income (expense)		
Investment income	1,750	7,304
Interest expense		(3,011)
	1,750	4,293
Net loss	$ (17,481)	$ (11,618)
Net loss per share, basic and diluted	$ (0.22)	$ (0.15)
Weighted average shares outstanding, basic and diluted	79,498	78,493

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2009
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity	Loss
Balance, December 31, 2008	2,249	$ 2	77,642	$ 78	$ 1,294,813	$ (875,927)	$ (114)	$ 418,852	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			117		1,038			1,038	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock-based compensation expense					7,654			7,654	
Net loss						(17,481)		(17,481)	$ (17,481)
Change in net unrealized loss on marketable securities							(1,134)	(1,134)	(1,134)
Balance, March 31, 2009	2,247	$ 2	77,842	$ 78	$ 1,304,896	$ (893,408)	$ (1,248)	$ 410,320	$ (18,615)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Three months ended March 31,	
	2009	2008
Cash flows from operating activities		
Net loss	$ (17,481)	$ (11,618)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,724	2,946
Non-cash compensation expense	7,654	8,286
Changes in assets and liabilities		
Increase in accounts receivable	(12,997)	(14,640)
(Increase) decrease in prepaid expenses and other assets	(8,611)	1,493
Increase in deferred revenue	3,194	3,200
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	15,318	(7,564)
Total adjustments	7,282	(6,279)
Net cash used in operating activities	(10,199)	(17,897)
Cash flows from investing activities		
Purchases of marketable securities	(100,315)	(91,518)
Sales or maturities of marketable securities	82,694	132,509
Capital expenditures	(21,917)	(3,047)
Net cash (used in) provided by investing activities	(39,538)	37,944
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	1,038	1,903
Net cash provided by financing activities	1,038	1,903
Net (decrease) increase in cash and cash equivalents	(48,699)	21,950
Cash and cash equivalents at beginning of period	247,796	498,925
Cash and cash equivalents at end of period	$ 199,097	$ 520,875

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2008 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

Included in research and development expenses is the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare LLC, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. The Bayer HealthCare estimate is adjusted to agree with actual expenses for such quarter in the subsequent interim fiscal quarter.

Effective in the first quarter of 2009, the estimated useful lives of laboratory and other equipment, which is a component of property, plant, and equipment, has been extended from 3 - 5 years to 3 - 10 years. The effect of this change in estimate was to lower depreciation expense by $0.2 million for the first quarter of 2009. There was no impact on the net loss per share as a result of this change in estimate.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the three months ended March 31, 2009, the Company recognized as revenue $3.9 million of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At March 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $4.2 million and $0.8 million, respectively.

Cost of goods sold related to ARCALYST sales totaled $0.4 million for the three months ended March 31, 2009 and consisted primarily of royalties. To date, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At March 31, 2009, the Company had $0.3 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three months ended March 31, 2009 and 2008, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March 31,	
	2009	2008
Net loss (Numerator)	$ (17,481)	$ (11,618)
Weighted-average shares, in thousands (Denominator)	79,498	78,493
Basic and diluted net loss per share	$ (0.22)	$ (0.15)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2009 and 2008 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended March 31,	
	2009	2008
Stock Options:		
Weighted average number, in thousands	20,216	17,680
Weighted average exercise price	$ 17.55	$ 17.16
Restricted Stock:		
Weighted average number, in thousands	500	500
Convertible Debt:		
Weighted average number, in thousands		6,611
Conversion price		$ 30.25

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2009 and December 31, 2008 were $9.8 million and $7.0 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2008 and December 31, 2007 were $1.5 million and $1.7 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2008 and 2007 were $1.5 million and $1.1 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2009 and 2008, the Company contributed 81,086 and 58,575 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2009 and December 31, 2008 were $2.5 million and $1.7 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2008 and December 31, 2007 were $2.1 million and $2.2 million, respectively, of accrued interest income.

5. Fair Value of Financial Assets

The Company's assets that are measured at fair value on a recurring basis, and subject to the disclosure requirements of Statement of Financial Accounting Standards No. ("SFAS") 157, *Fair Value Measurements*, at March 31, 2009 and December 31, 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
Description	Fair Value at March 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities	$ 295,245	$ 3,138	$ 292,007	$ 100

		Fair Value Measurements at Reporting Date Using		
Description	Fair Value at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities	$ 278,015	$ 3,608	$ 247,307	$ 100

There were no realized or unrealized gains or losses related to the Company's Level 3 marketable securities for the three months ended March 31, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the quarters ended March 31, 2009 and 2008.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. During the three months ended March 31, 2009 and 2008, the Company did not record any charges for other-than-temporary impairment of its marketable securities. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2009 and December 31, 2008 consist of the following:

	March 31, 2009	December 31, 2008
Accounts payable	$ 17,779	$ 6,268
Payable to Bayer HealthCare		9,799
Accrued payroll and related costs	8,352	5,948
Accrued clinical trial expense	6,558	4,273
Accrued property, plant, and equipment expenses	8,069	5,994
Accrued expenses, other	4,074	3,886
	$ 44,832	$ 36,168

7. Comprehensive Loss

The Company presents comprehensive income (loss) in accordance with SFAS 130, *Reporting Comprehensive Income*. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. For the three months ended March 31, 2009 and 2008, the components of comprehensive loss are:

	Three months ended March 31,	
	2009	2008
Net loss	$ (17,481)	$ (11,618)
Change in net unrealized gain (loss) on marketable securities	(1,134)	658
Total comprehensive loss	$ (18,615)	$ (10,960)

8. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

9. Future Impact of Recently Issued Accounting Standards

In April 2009, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS 107, *Disclosures about Fair Value of Financial Instruments*, to require entities to provide disclosures about the fair value of financial instruments in interim financial information. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. In addition, an entity shall disclose in the body or in the accompanying notes of its summarized financial information for interim reporting periods and in its financial statements for annual reporting periods the fair value of all financial instruments for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial position, as required by SFAS 107. The Company is required to adopt FSP FAS 107-1 and APB 28-1 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 107-1 and APB 28-1 will have a material impact on the Company's financial statements.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP changes existing guidance for determining whether an impairment to debt securities is other than temporary; replaces the existing requirement that management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert, (*a*) it does not have the intent to sell the security; and (*b*) it is more likely than not it will not have to sell the security before recovery of its cost basis; requires that an entity recognize noncredit losses on held-to-maturity debt securities in other comprehensive income and amortize that amount over the remaining life of the security in a prospective manner by offsetting the recorded value of the asset unless the security is subsequently sold or there are additional credit losses; and requires entities to present the total other-than-temporary impairment in the statement of earnings with an offset for the amount recognized in other comprehensive income. When adopting FSP FAS 115-2 and FAS 124-2, entities are required to record a cumulative-effect adjustment as of the beginning of the period of adoption to reclassify the noncredit component of a previously recognized other-temporary impairment from retained earnings to accumulated other comprehensive income if the entity does not intend to sell the security and it is not more likely than not that the entity will be required to sell the security before recovery. The Company is required to adopt FSP FAS 115-2 and FAS 124-2 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 115-2 and FAS 124-2 will have a material impact on the Company's financial statements.

In April 2009, the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*. This FSP affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell the asset in an orderly transaction; clarifies and includes additional factors for determining whether there has been a significant decrease in market activity for an asset when the market for that asset is not active; and eliminates the proposed presumption that all transactions are distressed (not orderly) unless proven otherwise. The FSP instead requires an entity to base its conclusion about whether a transaction was not orderly on the weight of the evidence. The Company is required to adopt FSP FAS 157-4 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 157-4 will have a material impact on the Company's financial statements.

10. Subsequent Event - Amendment to Operating Lease

The Company leases laboratory and office facilities in Tarrytown, New York. In December 2006, the Company entered into a new agreement (which was amended in October 2007 and September 2008) to lease laboratory and office space at the Company's current Tarrytown location, including space that is now under construction and expected to be completed in mid-2009 (the "new facilities"). The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, the Company amended the operating lease agreement to increase the amount of space the Company will lease. As amended, the lease contains early termination options for the portion of the space that excludes the new facilities. Other terms and conditions, as previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, the Company terminated an April 2008 sublease for space in Tarrytown, New York.

In connection with the April 2009 amendment to the operating lease, the Company's total estimated future minimum noncancelable lease commitments under operating leases, previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, will increase to $9.4 million, $14.5 million, $14.7 million, $13.7 million, and $15.1 million for the years ended December 31, 2009, 2010, 2011, 2012, and 2013, respectively, and increase to $182.5 million, in the aggregate, for years subsequent to 2013.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST, which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our clinical development and manufacturing capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*™) may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using *VelocImmune*. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) – Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped $10.7 million of ARCALYST to our distributors in 2008, and $4.3 million during the first quarter of 2009. ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is the only therapy approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

In March 2008, ARCALYST became available for prescription in the United States and we transitioned the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. In 2009, we expect to ship $15-20 million of ARCALYST to our U.S. distributors. In July 2008, we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for ARCALYST for the treatment of CAPS in the European Union.

Clinical Programs:

1. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in four Phase 3 trials that are evaluating combinations of aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer (called VELOUR) in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine (VANILLA). A third trial is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel (VITAL). The fourth trial is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone (VENICE). All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. At the end of the first quarter of 2009, each of the four Phase 3 trials was approximately one-half enrolled, and initial data from the Phase 3 program are expected are 2010. In addition, a Phase 2 study of aflibercept in 1st-line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (AFFIRM) began recruiting patients in January 2009.

Aflibercept is also being studied in a Phase 2 single-agent study in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA). This trial is now fully enrolled and initial data from this trial are expected by mid-2009. The FDA has granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) collaborate on the development and commercialization of aflibercept globally. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also initiated a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) in late 2008. Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare have also announced plans to initiate a Phase 3 program later this year of VEGF Trap-Eye in the treatment of Central Retinal Vein Occlusion (CRVO). Dosing of the first patient in this Phase 3 program will entitle us to receive a $20.0 million milestone payment.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc./Roche), an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 mg and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with ranibizumab dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. We and Bayer Healthcare expect to complete enrollment of the VIEW 1 and VIEW 2 trials in 2009 and initial data are expected in late 2010.

We and Bayer HealthCare have conducted a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. Study results were reported at the 2008 annual meeting of the Retina Society.

In this double-masked Phase 2 trial, known as CLEAR-IT 2, 157 patients were initially treated for 3 months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial 3-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 milligrams (mg) for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters ($p<0.0001$ versus baseline) and 5.4 letters ($p<0.085$ versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns ($p<0.0001$ versus baseline) and 125 microns ($p<0.0001$ versus baseline) at week 52, respectively.

After week 12 to week 52 in the PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Eighteen month results of the extension stage are scheduled to be presented on May 4, 2009 at the 2009 Association for Research in Vision and Ophthalmology (ARVO) meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters ($p<0.0001$ versus baseline) at the 3-month primary endpoint of the original Phase 2 study, 8.4 letters ($p<0.0001$ versus baseline) at one year, and 7.1 letters ($p<0.0001$ versus baseline) at month 6 of the extension stage. Thus, after 18 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 3.5 injections over the 15-month PRN dosing phase that extended from month 3 to month 18.

Among all the patients in the Phase 2 wet AMD study, VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and two arterial thrombotic events; these were deemed not to be drug-related. Three deaths were reported—one patient with pancreatic cancer, one patient with squamous cell carcinoma of the lung, and one patient with pulmonary hypertension (a pre-existing condition). The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The recently initiated Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study is expected to complete enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia by the end of 2009. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and other diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare. In 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and can earn up to $90 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. ARCALYST® (rilonacept) – Inflammatory Diseases

We are evaluating ARCALYST in gout, a disease where as in CAPS, IL-1 may play an important role in pain and inflammation. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, three of which are currently enrolling patients. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 clinical development program also includes a separate placebo-controlled safety study (RE-SURGE). We expect to report initial data from the Phase 3 program in 2010.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody, and to receive 45% of net profits on sales of the antibody product, in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe. Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to ARCALYST.

4. Monoclonal Antibodies

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune®* technology. The first therapeutic antibodies to enter clinical development under the collaboration are REGN88 and REGN475. REGN88, an antibody to the interleukin-6 receptor (IL-6R) is being evaluated in rheumatoid arthritis. REGN475, an antibody to Nerve Growth Factor (NGF) that binds NGF selectively without cross-reacting with other members of the neurotrophin family (such as neurotrophin-3, neurotrophin-4, and BDNF), is being developed for the treatment of pain. In addition, a Phase 1 trial is in the process of being initiated to evaluate REGN421, an antibody to Delta-like ligand-4 (Dll4), in patients with advanced malignancies. Over the course of the next several years, we and sanofi-aventis plan to advance an average of two to three new fully human monoclonal antibodies into clinical development each year.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST® (rilonacept), as well as aflibercept, and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

VelociSuite™

VelociSuite consists of *VelocImmune®*, *VelociGene®*, *VelociMouse®*, *and VelociMab™*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron's VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

Antibody Collaboration with sanofi-aventis

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $75 million of research from the collaboration's inception through December 31, 2008 and will fund up to $100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made $20.0 million annual, non-refundable payments to us in February 2007, 2008, and 2009. AstraZeneca is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next additional payment or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two $20.0 million annual, non-refundable payments to us, one in April 2007 and the other in June 2008. Astellas is required to make up to four additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Academic *VelocImmune®* Investigators' Program

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. In March 2009, we entered into a similar agreement with The University of Texas Southwestern Medical Center at Dallas. Under the agreements, scientists at these academic institutions will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay to the appropriate institution a low single-digit royalty on ensuing product sales.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene*® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended in September 2008, we are entitled to receive a minimum of $24.5 million over the five-year period beginning September 2006, including $1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and angiopoietins seems to be of value in either promoting or blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We are in the process of initiating Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune*® technology.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating lead monoclonal antibodies in relevant preclinical models.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting *in vivo* and *in vitro* experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2009, we had a cumulative loss of $893.4 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2009 and plans over the next 12 months are as follows:

Clinical Program	2009 Events to Date	2009-10 Plans (next 12 months)
ARCALYST® (rilonacept; also known as IL-1 Trap)	• Initiated patient enrollment in the Phase 3 program evaluating ARCALYST in the prevention of gout flares associated with the initiation of urate-lowering drug therapy and in the treatment of acute gout attacks	• Continue enrollment in the Phase 3 program in gout
Aflibercept (VEGF Trap - Oncology)	• Initiated a Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy • Achieved approximately 50% enrollment in each of the Phase 3 studies	• Report results of a Phase 2 single-agent study in SMA • Continue enrollment of the four Phase 3 studies
VEGF Trap-Eye (intravitreal injection)		• Complete enrollment in VIEW 1 and VIEW 2 trials • Continue enrolling patients in the Phase 2 DME trial • Initiate a Phase 3 CRVO program
Monoclonal Antibodies	• Initiated a Phase 1 trial for REGN475 (anti-NGF) in healthy volunteers	• Initiate a Phase 1 trial for REGN421(anti Dll4) in oncology • Report data from a Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis • Initiate multiple Phase 2 trials for REGN475 in pain indications • Advance additional antibody candidate(s) into clinical development

Results of Operations

Three Months Ended March 31, 2009 and 2008

Net Loss:

Regeneron reported a net loss of $17.5 million, or $0.22 per share (basic and diluted), for the first quarter of 2009 compared to a net loss of $11.6 million, or $0.15 per share (basic and diluted), for the first quarter of 2008. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher contract research and development revenue in connection with our antibody collaboration with sanofi-aventis and net product sales of ARCALYST® (rilonacept) for the treatment of CAPS.

Revenues:

Revenues for the three months ended March 31, 2009 and 2008 consist of the following:

(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis	$49.6	$35.7
Bayer HealthCare	10.0	9.0
Other	1.5	1.7
Total contract research & development revenue	61.1	46.4
Technology licensing revenue	10.0	10.0
Net product sales	3.9	
Total revenue	$75.0	$56.4

The contract and research development revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Contract Research & Development Revenue	Three months ended March 31,	
(In millions)	2009	2008
Aflibercept:		
Regeneron expense reimbursement	$ 5.4	$ 11.7
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total aflibercept	7.9	13.8
Antibody:		
Regeneron expense reimbursement	38.4	19.3
Recognition of deferred revenue related to up-front payment	2.6	2.6
Recognition of revenue related to *VelocImmune*® agreement	0.7	
Total antibody	41.7	21.9
Total sanofi-aventis contract research & development revenue	$ 49.6	$ 35.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first quarter of 2009, compared to the same period in 2008, primarily due to lower costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in the first quarter of 2009 compared to the same period in 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of March 31, 2009, $49.9 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In the first quarter of 2009, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $22.7 million under the discovery agreement and $15.7 million of development costs under the license agreement, compared to $15.1 million and $4.2 million, respectively, in the first quarter of 2008. Higher sanofi-aventis' reimbursements in the first quarter of 2009 compared to the same period in 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for REGN88, REGN421, and REGN475 under the license agreement.

Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' $85.0 million up-front payment. As of March 31, 2009, $71.0 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August, 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. For the three months ended March 31, 2009, we recognized $0.7 million of revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of revenue related to a non-refundable $75.0 million up-front payment and $20.0 million non-substantive milestone payment.

Bayer HealthCare Contract Research & Development Revenue	**Three months ended March 31,**	
(In millions)	**2009**	**2008**
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 7.5	$ 5.7
Recognition of deferred revenue related to up-front and milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	$ 10.0	$ 9.0

In the first quarter of 2009, cost-sharing of Regeneron VEGF Trap-Eye development expenses increased, compared to the same period in 2008, primarily due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD and Phase 2 trial in DME. Recognition of deferred revenue related to Bayer's up-front and milestone payments decreased in the first quarter of 2009 compared to the same period in 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of March 31, 2009, $64.2 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue in the first quarter of 2009 and 2008 includes $1.5 million and $1.1 million, respectively, in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first quarter of both 2009 and 2008, we recognized $10.0 million of technology licensing revenue related to these agreements.

For the three months ended March 31, 2009, we recognized as revenue $3.9 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At March 31, 2009, deferred revenue related to ARCALYST net product sales totaled $4.2 million.

Expenses:

Total operating expenses increased to $94.2 million in the first quarter of 2009 from $72.3 million in the same period of 2008. Our average headcount increased to 938 in the first quarter of 2009 from 714 in the same period of 2008 principally as a result of our expanding research and development activities which are primarily attributable to the sanofi-aventis antibody collaboration.

Operating expenses in the first quarter of 2009 and 2008 include a total of $7.7 million and $8.3 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended March 31, 2009		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 77.4	$ 4.7	$82.1
Selling, general, and administrative	8.7	3.0	11.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 86.5	$ 7.7	$94.2

	For the three months ended March 31, 2008		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 56.4	$ 4.9	$61.3
Selling, general, and administrative	7.6	3.4	11.0
Total operating expenses	$ 64.0	$ 8.3	$72.3

Research and Development Expenses:

Research and development expenses increased to $82.1 million in the first quarter of 2009 from $61.3 million in the same period of 2008. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2009 and 2008:

	For the three months ended March 31,		
Research and Development Expenses *(In millions)*	2009	2008	Increase (Decrease)
Payroll and benefits (1)	$22.9	$19.2	$ 3.7
Clinical trial expenses	19.3	8.5	10.8
Clinical manufacturing costs (2)	14.1	14.7	(0.6)
Research and preclinical development costs	8.4	5.5	2.9
Occupancy and other operating costs	10.4	6.8	3.6
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	7.0	6.6	0.4
Total research and development	$82.1	$61.3	$20.8

(1) Includes $4.0 million and $4.2 million of Non-cash Compensation Expense for the three months ended March 31, 2009 and 2008, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million of Non-cash Compensation Expense for both the three months ended March 31, 2009 and 2008.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD and Phase 2 trial in DME, (ii) ARCALYST, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibodies, primarily related to REGN88 in rheumatoid arthritis. Clinical manufacturing costs decreased due to lower costs related to manufacturing aflibercept clinical supplies, partially offset by higher costs related to manufacturing clinical supplies of ARCALYST and monoclonal antibodies, including REGN88. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new operating lease for our Tarrytown, New York facilities, which commenced in June 2008. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses slightly increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which is being conducted by Bayer HealthCare.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs (including ARCALYST for the treatment of CAPS prior to receipt of marketing approval from the FDA in February 2008) are shown below:

Project Costs	For the three months ended March 31,		
(In millions)	2009	2008	Increase (Decrease)
ARCALYST® (rilonacept)	$17.9	$ 8.0	$ 9.9
Aflibercept	4.2	10.1	(5.9)
VEGF Trap-Eye	20.8	16.6	4.2
REGN88	9.0	3.8	5.2
REGN421 and REGN475	4.9		4.9
Other research programs & unallocated costs	25.3	22.8	2.5
Total research and development expenses	$82.1	$61.3	$20.8

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

Selling, General, and Administrative Expenses:

Selling, general, and administrative expenses increased to $11.7 million in the first quarter of 2009 from $11.0 million in the same period of 2008 due to (i) higher selling expenses related to ARCALYST, (ii) higher compensation expense due primarily to increases in administrative headcount to support our expanded research and development activities, and (iii) higher administrative facility-related costs arising principally in connection with our higher headcount and the new operating lease for our Tarrytown, New York facilities, which commenced in June 2008.

Cost of Goods Sold:

In the third quarter of 2008, we began recognizing revenue and cost of goods sold from product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for the first quarter of 2009 was $0.4 million and consisted primarily of royalty and other period costs related to ARCALYST commercial supplies.

Other Income and Expense:

Investment income decreased to $1.8 million in the first quarter of 2009 from $7.3 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter of 2008. Interest expense was $3.0 million in the first quarter of 2008 and related to $200.0 million of formerly outstanding 5.5% Convertible Senior Subordinated Notes which we either repurchased or repaid in full during 2008.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST product revenue, and investment income.

Three months ended March 31, 2009 and 2008

At March 31, 2009, we had $496.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with $527.5 million at December 31, 2008. In February 2009, we received a $20.0 million annual, non-refundable payment in connection with our non-exclusive license agreement with AstraZeneca.

Cash Used in Operations:

Net cash used in operations was $10.2 million in the first quarter of 2009 compared to $17.9 million in the first quarter of 2008. Our net losses of $17.5 million in the first quarter of 2009 and $11.6 million in the first quarter of 2008 included $7.7 million and $8.3 million, respectively, of Non-cash Compensation Expense.

At March 31, 2009, accounts receivable increased by $13.0 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by $8.6 million at March 31, 2009 compared to end-of-year 2008 due primarily to higher prepaid clinical trial costs. At March 31, 2009, accounts payable, accrued expenses, and other liabilities increased by $15.3 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll costs, and capital expenditures, primarily for tenant improvements and related costs in connection with our new leased facilities in Tarrytown, New York, partially offset by a lower cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration.

At March 31, 2008, accounts receivable increased by $14.6 million, compared to end-of-year 2007, primarily due to higher receivable balances related to our collaborations with sanofi-aventis. Accounts payable, accrued expenses, and other liabilities decreased by $7.6 million at March 31, 2008, compared to end-of-year 2007, due primarily to reductions in accrued payroll costs and the amount of the cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was $39.5 million in the first quarter of 2009 compared to net cash provided by investing activities of $37.9 million in the same period of 2008, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first quarter of 2009, purchases exceeded sales or maturities of marketable securities by $17.6 million, whereas in the first quarter of 2008, sales or maturities exceeded purchases of marketable securities by $41.0 million. In addition, cash used for capital expenditures totaled $21.9 million in the first three months of 2009, primarily for tenant improvements and related costs in connection with our new leased facilities in Tarrytown.

Cash Provided by Financing Activities:

Cash provided by financing activities decreased to $1.0 million in the first quarter of 2009 from $1.9 million in the same period in 2008 due to a decrease in issuances of Common Stock in connection with exercises of employee stock options.

Fair Value of Marketable Securities:

At March 31, 2009 and December 31, 2008, we held marketable securities whose aggregate fair value totaled $295.2 million and $278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2009		December 31, 2008	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$ 131.0	44%	$ 113.9	41%
U.S. government agency securities	59.9	20%	58.3	21%
U.S. government-guaranteed corporate bonds	48.9	17%	29.8	11%
U.S. government guaranteed collateralized mortgage obligations	11.3	4%	17.4	6%
Corporate bonds	32.1	11%	37.1	13%
Asset-backed securities	8.8	3%	17.8	7%
Other	3.2	1%	3.7	1%
Total marketable securities	$ 295.2	100%	$ 278.0	100%

In addition, at March 31, 2009 and December 31, 2008, we had $200.8 million and $249.5 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During the first quarter of 2009, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift toward higher quality securities, which we initiated in 2008, continues to reduce the risk profile, as well as the overall yield, of our portfolio. In particular, we continue to reduce the proportion of asset-backed securities and corporate bonds in our portfolio.

Capital Expenditures:

Our additions to property, plant, and equipment totaled $24.7 million and $2.8 million for the first three months of 2009 and 2008, respectively. During the remainder of 2009, we expect to incur, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and the new Tarrytown facilities approximately $80 to $90 million in capital expenditures of which up to approximately $50 million is reimbursable at our option from our landlord under the terms of our Tarrytown operating lease.

Amendment to Operating Lease – Tarrytown, New York Facilities:

We currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new operating lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, including approximately 230,000 square feet in new facilities that are currently under construction and expected to be completed in mid-2009. The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, we amended the operating lease agreement to increase the amount of space we will lease to approximately 389,500 square feet. As amended, the lease contains early termination options on approximately 159,500 square feet of space. Other terms and conditions, as previously described in our Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, we terminated a sublease for 16,200 square feet of space in Tarrytown, New York.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55-65% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST® (rilonacept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 15-20% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 sales of ARCALYSTfor the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with the April 2009 amendment to our operating lease agreement in Tarrytown, New York, as described above, our funding requirements for operating leases, previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008, will increase (i) from $9.1 million to $9.4 million for the year ending December 31, 2009, (ii) from $26.8 million to $29.2 million for the two-year period beginning January 1, 2010, (iii) from $27.2 million to $28.8 million for the two-year period beginning January 1, 2012, and (iv) from $167.0 million to $182.5 million for the fiscal years beginning January 1, 2014 and thereafter.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund selected preclinical and clinical development programs.

Other than letters of credit totaling $1.7 million, including a $1.6 million letter of credit issued to our landlord in connection with our operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2009, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In April 2009, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS 107, *Disclosures about Fair Value of Financial Instruments*, to require entities to provide disclosures about the fair value of financial instruments in interim financial information. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. In addition, an entity shall disclose in the body or in the accompanying notes of its summarized financial information for interim reporting periods and in its financial statements for annual reporting periods the fair value of all financial instruments for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial position, as required by SFAS 107. We are required to adopt FSP 107-1 and APB 28-1 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP 107-1 and APB 28-1 will have a material impact on our financial statements.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP changes existing guidance for determining whether an impairment to debt securities is other than temporary; replaces the existing requirement that management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert: (*a*) it does not have the intent to sell the security; and (*b*) it is more likely than not it will not have to sell the security before recovery of its cost basis; requires that an entity recognize noncredit losses on held-to-maturity debt securities in other comprehensive income and amortize that amount over the remaining life of the security in a prospective manner by offsetting the recorded value of the asset unless the security is subsequently sold or there are additional credit losses; and requires entities to present the total other-than-temporary impairment in the statement of earnings with an offset for the amount recognized in other comprehensive income. When adopting FSP FAS 115-2 and FAS 124-2, entities are required to record a cumulative-effect adjustment as of the beginning of the period of adoption to reclassify the noncredit component of a previously recognized other-temporary impairment from retained earnings to accumulated other comprehensive income if the entity does not intend to sell the security and it is not more likely than not that the entity will be required to sell the security before recovery. We are required to adopt FSP FAS 115-2 and FAS 124-2 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 115-2 and FAS 124-2 will have a material impact on our financial statements.

In April 2009 the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*. This FSP affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell the asset in an orderly transaction; clarifies and includes additional factors for determining whether there has been a significant decrease in market activity for an asset when the market for that asset is not active; and eliminates the proposed presumption that all transactions are distressed (not orderly) unless proven otherwise. The FSP instead requires entities to base its conclusion about whether a transaction was not orderly on the weight of the evidence. We are required to adopt FSP FAS 157-4 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 157-4 will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate, asset-backed, and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a $1.6 million and $1.8 million decrease in the fair value of our investment portfolio at March 31, 2009 and 2008, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In 2007, we recognized a $5.9 million charge related to marketable securities from two issuers which we considered to be other than temporarily impaired in value. In 2008, an additional $0.7 million impairment charge was recognized related to one of these securities and a $1.8 million charge was recognized related to another marketable security which we considered to be other than temporarily impaired in value.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2009, we had a cumulative loss of $893.4 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of March 31, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled $496.0 million and represented 73% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. (SFAS) 115, *Accounting for Certain Investments in Debt and Equity Securities*. Marketable securities totaled $295.2 million at March 31, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income. For example, during the year ended December 31, 2008, we recorded charges for other-than-temporary impairments totaling $2.5 million related to two marketable securities in our investment portfolio. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying aflibercept, VEGF Trap-Eye, ARCALYST® (rilonacept), and our antibody candidates in a wide variety of indications. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST in only a small number of patients with CAPS. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (Amgen, Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech/Roche that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech/Roche could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech/Roche may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech/Roche's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech/Roche and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech/Roche patent, then we may need to obtain a license from Genentech/Roche, should one be available. Genentech/Roche has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech/Roche's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. Although we obtained regulatory approval for ARCALYST® (rilonacept) for the treatment of CAPS in the United States, we may be unable to obtain regulatory approval of ARCALYST in any other country or in any other indication. Regulatory agencies outside the United States may require additional information or data with respect to any future submission for ARCALYST for the treatment of CAPS.

If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST for the treatment of CAPS or any of our product candidates in those countries.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and possible legislation which could ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the manufacture, development, or ultimate commercialization of our product candidates.

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures or a business interruption at our manufacturing facility in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST and our product candidates at our manufacturing facility in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, or other problems at the facility.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. As a result, there may be too few patients with CAPS to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech/Roche has an approved VEGF antagonist, Avastin® (bevacizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline plc. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech/Roche's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech/Roche) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, ranibizumab (Lucentis®), for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech/Roche's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech/Roche) to Avastin (Genentech/Roche) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech/Roche) and the potential off-label use of Avastin (Genentech/Roche) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech/Roche), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech/Roche) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® (rilonacept). This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis has stated that its IL-1 antibody demonstrated long-lasting clinical remission in patients with CAPS and that its clinical candidate could develop into a major therapeutic advance in the treatment of CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST in the United States for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Our move to new facilities in mid-2009 could lead to disruptions in our business operations.

We plan to move most of our laboratories and headquarters to new facilities in mid-2009. There is a risk that this physical move could lead to damage to equipment or other business assets or the loss of important data, or that we could encounter problems with our new facilities, which could disrupt or delay our business operations.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their party patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 14, 2009, our five largest shareholders plus Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 52.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2009. As of April 14, 2009, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.0% of the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 14, 2009, holders of Class A Stock held 22.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 14, 2009:

- our current executive officers and directors beneficially owned 13.3% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2009, and 28.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2009; and

- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 52.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2009. In addition, these six shareholders held 57.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 14, 2009.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1	- Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers.
10.2	- Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers.
10.3	- Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., entered into as of April 29, 2009.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: April 30, 2009

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Notice of Grant of Stock Options and Option Agreement for Time Vesting Option Awards

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[OPTIONEE NAME]
[OPTIONEE ADDRESS

Option Number: [ ]
Plan: 04
ID [ ]

Effective <date> (the Grant Date) you have been granted a [Non-Qualified Stock Option] [Incentive Stock Option] to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the Company) stock at [$] per share.

The total option price of the shares granted is [$].

[Shares in each period will become fully vested on the date shown.

[Shares	Vest Type	Full Vest	Expiration Date
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]]

The [Non-Qualified Stock Option] [Incentive Stock Option] expires on [ ]*** (the "Expiration Date").

You and the Company agree that these options are granted under and governed by the terms and conditions of the Company's Amended and Restated 2000 Long-Term Incentive Plan and the enclosed Option Agreement, both of which are attached and made a part of this document.

** Options for executive officers will vest in approximately equal annual 25% installments. Full Vest Dates will occur on the first, second, third and fourth anniversaries of the Grant Date. Options for non-employee directors will vest in approximately equal annual 33-1/3% installments. Full Vest Dates will occur on the first, second, and third anniversaries of the Grant Date.

*** Date to be 10 years from the Grant Date.

REGENERON PHARMACEUTICALS, INC.
OPTION AGREEMENT
PURSUANT TO THE
2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee (or member of the Board of Directors) named on the *Notice of Grant of Stock Options* (the "Grantee");

WHEREAS, the Grantee is an employee or member of the Board of Directors of the Company and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's Common Stock ($.001 par value) (the "Common Stock") as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth here, the option to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share (the "Option") as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option is exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7 (c)(1) & (2), the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having a Fair Market Value (as measured on the date of exercise) equal to the Option exercise price. The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall be entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (collectively, the Company and all Subsidiaries shall be referred to herein as the "Employer" and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on the Full Vest Dates. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by the Employer (or providing services as a member of the Board of Directors, as the case may be) and all unvested Options shall be forfeited at such time.

(c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer (or services as a member of the Board of Directors) if the Grantee's employment with the Employer (or services a member of the Board of Directors) is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment (or service as member of the Board of Directors) (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, (2) any lump sum severance based on a multiple of base salary or bonus, (3) any other cash amounts payable to the Grantee, (4) any benefits valued as parachute payments, and (5) acceleration of vesting of any equity not covered by (1) above.

3. **Option Term.** (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7 (e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement, (C) one year after the termination if such termination is due to the Grantee's death or long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.

(b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Company and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee; (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "good reason" (or words of like import), as defined under such agreement or plan.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Stockholder. The Grantee shall have no rights as a stockholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates for such shares. No adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

6. Compliance with Law and Regulations. This award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated herein by reference, and any capitalized term used but not defined herein shall have the same meaning as in the Plan. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment or service, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

Notice of Grant of Stock Options
and Option Agreement for Performance
Vesting Option Awards

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[OPTIONEE NAME]
[OPTIONEE ADDRESS

Option Number: [ ]
Plan: 04
ID [ ]

Effective <date> (the Grant Date) you have been granted a Non-Qualified Stock Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the Company) stock at [$] per share.

The total option price of the shares granted is [$].

Stock options granted pursuant to this award will be eligible to vest on [ ]*. The number of stock options that will vest on that date will be determined based on the total number of points that are earned according to the table below during the period commencing on [ ] and ending on [ ]* (the Performance Measurement Period):

Total Points	Stock Options to Vest on [ ]*
[ ] or less	0
[ ]	[ ]
[ ]	[ ]
[ ]	[ ]
[ ] or more	[ ]

Total points in the table set forth above will be calculated based on the following criteria as achieved during the Performance Measurement Period:

[Description of performance criteria and allocation of points for achieving specific milestones]

[For the avoidance of doubt, points may be earned upon achievement of the specified criteria by or on behalf of the Company or any subsidiary of the Company, including by any other entity pursuant to or in connection with any license or collaboration agreement under which such entity has rights to develop the Drug Candidate.]

[Notwithstanding the foregoing, if [insert certain criteria] have not been achieved during the Performance Measurement Period, then the number of stock options from this award that will vest on [ ]* may not exceed [ ] unless otherwise determined by the Compensation Committee or there is an acceleration of this stock option award following a Change in Control pursuant to any employment agreement, change in control agreement or similar agreement in effect between the Grantee and the Company.

Notwithstanding anything to the contrary set forth herein, the Compensation Committee of the Board of Directors of the Company shall have the discretion to cause or accelerate the vesting of any or all of the stock options granted pursuant to this award.

The Compensation Committee of the Board of Directors of the Company shall have the authority in its sole discretion to determine whether the criteria required for earning the points in the table set forth above were achieved.

The Non-Qualified Stock Option expires on [10 years from the Grant Date].

You and the Company agree that these options are granted under and governed by the terms and conditions of the Company's Amended and Restated 2000 Long-Term Incentive Plan and the enclosed Option Agreement, both of which are attached and made a part of this document.

_____

* This date will be the last day of the Performance Measurement Period.

REGENERON PHARMACEUTICALS, INC.
OPTION AGREEMENT
PURSUANT TO THE
2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee [(or member of the Board of Directors)]* named on the *Notice of Grant of Stock Options* (the "Grantee");

WHEREAS, the Grantee is an employee [or member of the Board of Directors]* of the Company and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's Common Stock ($.001 par value) (the "Common Stock") as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth here, the option to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share (the "Option") as shown on the *Notice of Grant of Stock Options*. [No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").]* [Notwithstanding the foregoing, the Option will not qualify as an Incentive Stock Option, among other events, (i) if the Grantee disposes of the Common Stock acquired pursuant to the Option at any time during the two year period following the date of this Agreement or the one year period following the date on which the Option is exercised, or (ii) if the Grantee is not employed by the Company or a subsidiary of the Company within the meaning of Section 424 of the Code (a "Subsidiary") at all times during the period beginning on the date of this Agreement and ending on the day three months before the date of exercise of the Option, or (iii) to the extent the aggregate fair market value (determined as of the time the Option is granted) of the stock subject to Incentive Stock Options which become exercisable for the first time in any calendar year exceeds $100,000. To the extent that the Option does not qualify as an Incentive Stock Option, it shall constitute a separate Non-Qualified Stock Option.]**

2. Vesting; Exercise. (a) The Option is exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7 (c)(1) & (2), the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. [In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having a Fair Market Value (as measured on the date of exercise) equal to the Option exercise price.]* The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall be entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (collectively, the Company and all Subsidiaries shall be referred to herein as the "Employer" and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on the Full Vest Dates. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by the Employer [(or providing services as a member of the Board of Directors, as the case may be)]* and all unvested Options shall be forfeited at such time.

(c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer [(or services as a member of the Board of Directors)]* if the Grantee's employment with the Employer [(or services a member of the Board of Directors)]* is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment [(or service as member of the Board of Directors)]* (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, (2) any lump sum severance based on a multiple of base salary or bonus, (3) any other cash amounts payable to the Grantee, (4) any benefits valued as parachute payments, and (5) acceleration of vesting of any equity not covered by (1) above.

3. **Option Term.** (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7 (e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement, (C) one year after the termination if such termination is due to the Grantee's death or long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.

(b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Company and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee; (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "good reason" (or words of like import), as defined under such agreement or plan.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Stockholder. The Grantee shall have no rights as a stockholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates for such shares. No adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

6. Compliance with Law and Regulations. This award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated herein by reference, and any capitalized term used but not defined herein shall have the same meaning as in the Plan. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment or service, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

---

* For Non-Qualified Stock Option Awards.

** For Incentive Stock Option Awards.

THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (this "Amendment") is entered into as of this 29th day of April, 2009 ("Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), and that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment" and, collectively with the Original Lease and the First Amendment, and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings", and each a "Building");

B. WHEREAS, Emisphere Technologies, Inc. ("Emisphere"), leases certain space from Landlord at 765 Old Saw Mill River Road (the "765 Building") pursuant to that certain Lease dated as of March 31, 1997, as the same may have been amended, supplemented or otherwise modified from time to time, the "Emisphere Lease");

C. WHEREAS, Emisphere, as sublessor, subleases to Tenant, as sublessee, approximately 13,652 rentable square feet of space (the "Regeneron Sublease Premises") in the Quad I & II Premises (as defined below) pursuant to that certain Sublease Agreement dated as of April 15, 2008 (the "Regeneron Sublease");

D. WHEREAS, Emisphere, as sublessor, subleases to PsychoGenics Inc. ("PsychoGenics"), as sublessee, approximately 2,275 rentable square feet of space (the "PsychoGenics Premises") in the Quad III & IV Premises (as defined below) pursuant to that certain Sublease dated as of January __[sic], 2008 (the "PsychoGenics Sublease");

E. WHEREAS, as of the date hereof, Landlord and Emisphere have terminated the Emisphere Lease and, consequently, the Regeneron Sublease and PsychoGenics Sublease have been terminated;

F. WHEREAS, Tenant desires to continue to occupy and lease directly from Landlord the Regeneron Sublease Premises, to surrender certain other space within the Buildings and to lease additional space in the 765 Building from Landlord; and

G. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Amendment, is referred to herein as the "Amended Lease."

2. Swap Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord (y) as of the Execution Date, the Regeneron Sublease Premises, and (z) as of May 1, 2009 (the "Swap Premises Commencement Date"), the portions of the following premises that are not part of the Regeneron Sublease Premises. The Quad I & II Premises and Quad III & IV Premises (including the Regeneron Sublease Premises) are referred to herein collectively as the "Swap Premises." The Swap Premises consist of approximately 77,178 rentable square feet.

a. Quad I Premises. Approximately 13,462 rentable square feet of space located on the second floor of the 765 Building, as shown on Exhibit A attached hereto (the "Quad I Premises");

b. Quad II Premises. Approximately 22,219 rentable square feet of space located on the second floor of the 765 Building, as shown on Exhibit A attached hereto (the "Quad II Premises" and, collectively with the Quad I Premises, the "Quad I & II Premises");

c. Quad III Premises. Approximately 20,748 rentable square feet of space located on the second floor of the 765 Building, as shown on Exhibit A attached hereto (the "Quad III Premises"); and

d. Quad IV Premises. Approximately 20,749 rentable square feet of space located on the second floor of the 765 Building, as shown on Exhibit A attached hereto (the "Quad IV Premises" and, collectively with the Quad III Premises, the "Quad III & IV Premises").

3. Surrender Premises. The parties acknowledge that, as part of the Additional Premises, Tenant currently leases approximately 35,681 rentable square feet in the North portion of the Building located at 777 Old Saw Mill River Road, as shown on Exhibit B attached hereto (the "Surrender Premises"). The Additional Premises less the Surrender Premises shall be referred to herein as the "Modified Additional Premises." Notwithstanding anything to the contrary in the Lease, the Term for the Surrender Premises shall expire on August 31, 2009, and Landlord and Tenant shall be released from each of their respective obligations under the Lease with respect to the Surrender Premises (including the payment of Rent), except for those obligations that expressly survive the expiration or earlier termination of the Lease.

4. Tenant's Pro Rata Shares. From and after the Execution Date until the Swap Premises Commencement Date, (a) the Premises shall be deemed to include the Regeneron Sublease Premises, (b) Tenant's Pro Rate Share of the 765 Building shall increase from 15.25% to 22.94%, (c) Tenant's Pro Rata Share of the Existing Project (based on Retained Premises, Additional Premises and Regeneron Sublease Premises only) shall increase from 15.75% to 17.57%, and (iv) Tenant's Pro Rata Share of the Entire Project shall increase from 31.29% to 32.52%. From and after the Swap Premises Commencement Date, Section 2.2 of the Lease is hereby deleted and replaced in its entirety with the following:

> The Premises, the Buildings, and certain related terms are defined as follows. In these definitions, each Rentable Area is expressed in rentable square footage. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under this Lease, including under Section 9.2.

Definition or Provision	Means the Following (As of the Swap Premises Commencement Date)
"Premises"	Retained Premises, New Premises, Additional Premises, and Swap Premises
"Buildings"	735 Building, 745 Building, 765 Building and 777 Building
Rentable Area of Premises	389,529
Rentable Area of Buildings	117,935 for 735 Building 111,708 for 745 Building 177,203 for 765 Building 311,104 for 777 Building
Rentable Area of Existing Project	751,648
Rentable Area of New Project	360,520
Rentable Area of Entire Project	1,112,168
Tenant's Pro Rata Share of Buildings	100% of 735 Building 100% of 745 Building 58.80 % of 765 Building 17.90% of 777 Building
Tenant's Pro Rata Share of the Existing Project (Based on Retained Premises, Additional Premises and Swap Premises only)	21.27%
Tenant's Pro Rata Share of the New Project (Based on New Premises only) Tenant's Pro Rata Share of Entire Project	63.70% 35.02%

5. Rent.

a. Basic Annual Rent. Commencing as of (i) the Swap Premises Commencement Date with respect to the Quad I Premises and (ii) September 1, 2009, with respect to the remainder of the Swap Premises (the relevant dates in (i) and (ii), the "Swap Premises Rent Commencement Date"), and continuing through the Term, Tenant shall pay Landlord Basic Annual Rent for the Swap Premises ("Swap Premises Basic Annual Rent") in the following amounts (in addition to Rent otherwise due under the Lease) and in accordance with the terms for payment of Basic Annual Rent set forth in the Lease:

Quad I Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly
Swap Premises Commencement Date – August 31, 2009	13,462	$26.50	$356,743.00 (to be prorated)	$29,728.58
September 1, 2009 – June 30, 2010	13,462	$28.00	$376,936.00 (to be prorated)	$31,411.33
July 1, 2010 – remainder of the Term	13,462	Swap Premises Basic Annual Rent to increase annually every July 1 by 2.5% of the then-current Swap Premises Basic Annual Rent applicable to Quad I Premises		
Quad II Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly
Swap Premises Rent Commencement Date – June 30, 2010	22,219	$28.00	$622,132.00	$51,844.33
July 1, 2010 – remainder of the Term	22,219	Swap Premises Basic Annual Rent to increase annually every July 1 by 2.5% of the then-current Swap Premises Basic Annual Rent applicable to Quad II Premises		
Quad III Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly
Swap Premises Rent Commencement Date – June 30, 2010	20,748	$26.50	$549,822 (to be prorated)	$45,818
July 1, 2010–June 30, 2011	20,748	$27.16	$563,515.68	$46,959.64
July 1, 2011–June 30, 2012	20,748	$27.84	$577,624.32	$48,135.36
July 1, 2012–June 30, 2013	20,748	$28.00	$580,944	$48,412.00

July 1, 2013–June 30, 2014	20,748	$28.00	$580,944	$48,412.00
July 1, 2014–remainder of Term	20,748	Swap Premises Basic Annual Rent to increase annually every July 1 by 2.5% of the then-current Swap Premises Basic Annual Rent applicable to Quad III Premises		
Quad IV Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly
Swap Premises Rent Commencement Date – June 30, 2010	20,749	$26.50	$549,848.50 (to be prorated)	$45,820.71
July 1, 2010–June 30, 2011	20,749	$27.16	$563,542.84	$46,961.90
July 1, 2011–June 30, 2012	20,749	$27.84	$577,652.16	$48,137.68
July 1, 2012–June 30, 2013	20,749	$28.00	$580,972.00	$48,414.33
July 1, 2013–June 30, 2014	20,749	$28.00	$580,972.00	$48,414.33
July 1, 2014–remainder of Term	20,749	Swap Premises Basic Annual Rent to increase annually every July 1 by 2.5% of the then-current Swap Premises Basic Annual Rent applicable to Quad IV Premises		

b. Operating Expenses.

i. In addition to Swap Premises Basic Annual Rent, commencing as of the Swap Premises Rent Commencement Date, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the applicable portion of the Swap Premises.

ii. Notwithstanding anything in the Amended Lease to the contrary, and solely with respect to the Quad II Premises and the Quad III & IV Premises, commencing as of the Swap Premises Commencement Date and continuing until (but not including) the Swap Premises Rent Commencement Date, Tenant shall pay to Landlord monthly, on the first day of each month as Additional Rent, a fixed amount of One Hundred Twenty Thousand Five Hundred Dollars ($120,500). The parties hereby agree and confirm that the foregoing amount shall be the sole obligation of Tenant with respect to Operating Expenses for the Quad II Premises and the Quad III & IV Premises during such period.

iii. For the avoidance of doubt, HVAC for the Additional Premises and the Swap Premises shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises.

6. Rent Credit. Tenant shall be entitled to the following Rent credits:

a. Effective as of December 1, 2009, a Rent credit equal to Five Hundred Thousand Dollars ($500,000) to be applied against any portion of Rent due to Landlord under the Amended Lease; and

b. Effective as of December 1, 2012, a Rent credit equal to One Million Fifty Thousand Three Hundred Dollars ($1,050,300) to be applied against any portion of Rent due to Landlord under the Amended Lease (except that the foregoing credit shall not be applicable to cure a monetary default of Tenant).

7. Swap Premises Term Expiration Date. The Term for the Swap Premises shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Lease (as amended by this Amendment), and (b) Tenant's termination options set forth in Section 13 below.

8. Lease Extension Options. From and after the Swap Premises Commencement Date, the first paragraph of Article 44 of the Lease is hereby deleted and replaced with the following:

> 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises or (e) the Swap Premises. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option (as defined below)has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

9. Delivery of Possession.

a. Tenant acknowledges that it is currently in possession of and occupies the Regeneron Sublease Premises. Landlord shall deliver to Tenant (i) on the Execution Date, the Regeneron Sublease Premises for construction of the Swap Premises Tenant Improvements (as defined below), and (ii) on the Swap Premises Commencement Date, the remainder of the Swap Premises for possession, occupancy and construction of the Swap Premises Tenant Improvements. As of each such date, Tenant's possession and occupancy of the applicable portions of the Swap Premises shall be governed by and pursuant to the Amended Lease; provided, however, that Tenant shall have no obligation to pay Swap Premises Basic Annual Rent with respect to its occupancy and possession of the Swap Premises prior to the applicable Swap Premises Rent Commencement Date. Landlord shall permit Tenant, accompanied by an employee of Landlord, to enter the portion of the Swap Premises that is not the Regeneron Sublease Premises at a time mutually acceptable to Landlord and Tenant (but in no event more than three (3) days prior to the Swap Premises Commencement Date) for the purpose of Tenant planning its move into the Swap Premises.

b. If Landlord fails to deliver all or a portion of the Swap Premises to Tenant on the Swap Premises Commencement Date (such portion, the "Late Delivery Premises"), then Tenant shall not be obligated to pay Base Rent or Operating Expenses with respect to the Late Delivery Premises until Landlord delivers the Late Delivery Premises to Tenant.

10. Tenant Improvements.

a. Landlord shall make available to Tenant a tenant improvement allowance of Ten Dollars ($10) per rentable square foot of the Quad I & II Premises (the "Quad I & II Premises TI Allowance") at any time after the Swap Premises Commencement Date until such time as Tenant has exercised a Quad I & II Termination Option (as defined below). Further, Landlord shall make available to Tenant a tenant improvement allowance of Twenty Dollars ($20) per rentable square foot of the Quad III & IV Premises (the "Quad III & IV Premises TI Allowance"). Up to Ten Dollars ($10) per rentable square foot of the Quad III & IV Premises TI Allowance (the "Phase 1 Quad III & IV Premises TI Allowance") shall be available to Tenant at any time after the Swap Premises Rent Commencement Date. The balance of the Quad III & IV Premises TI Allowance (not to exceed an additional Ten Dollars ($10) per rentable square foot (the "Phase 2 Quad III & IV Premises TI Allowance")) shall be available to Tenant at any time during the Term after June 30, 2013; provided that Tenant has not exercised a Quad III & IV Termination Option (as defined below). If Tenant has exercised a Quad III & IV Termination Option with respect to the Quad III Premises or the Quad IV Premises only, then Tenant shall still be entitled to its pro rata amount of the Phase 2 Quad III & IV Premises TI Allowance allocable to the non-terminated portion of the Quad III & IV Premises.

b. The Quad I & II Tenant Improvement Allowance and the Quad III & IV Tenant Improvement Allowance (collectively, the "Swap Premises TI Allowance") shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of Article 5 of the Lease, including, without limitation, the Disbursement Conditions, in order to finance improvements to the Swap Premises consistent with the provisions of the Lease and the Permitted Use (such improvements, the "Swap Premises Tenant Improvements"). Tenant shall be responsible for performing and completing the Swap Premises Tenant Improvements, and Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the Swap Premises Tenant Improvements, including, without limitation, the Swap Premises TI Allowance to the extent disbursed to Tenant, which construction oversight fee may be paid out of the Swap Premises TI Allowance.

11. Reduction in Additional Premises TI Allowance. The Additional Premises TI Allowance, as set forth in Section 10 of the Second Amendment, is hereby reduced by Three Hundred Fifty-Six Thousand Eight Hundred Ten Dollars ($356,810). For the avoidance of doubt, Landlord and Tenant acknowledge that the reduction in the Additional Premises TI Allowance results from Tenant surrendering the Surrender Premises, and that Tenant shall continue to have available to it, to the extent not previously disbursed, Ten Dollars ($10) per rentable square foot of the Modified Additional Premises.

12. Parking. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces on the South side of the Entire Project with respect to the Swap Premises. As of the Swap Premises Rent Commencement Date, Tenant shall be entitled to an additional two (2) parking spaces per thousand (1,000) rentable square feet of Swap Premises. In addition, Tenant's pro rata share of unreserved parking spaces on the North side of the Entire Project shall be reduced proportionately to reflect Tenant's surrendering of the Surrender Premises.

13. Termination Options:

a. Tenant shall be entitled to terminate the Lease with respect to (i) the entire Quad III Premises, (ii) the entire Quad IV Premises or (iii) the entire Quad III & IV Premises (each, a "Quad III & IV Termination Option," and collectively, the "Quad III & IV Termination Options"). In each case, upon not less than eighteen (18) months' prior written notice to Landlord, effective as of (l) June 30, 2013, upon payment to Landlord of Fifteen and 57/100 Dollars ($15.57) per rentable square foot of terminated space, (m) June 30, 2014, upon payment to Landlord of Fourteen and 16/100 Dollars ($14.16) per rentable square foot of terminated space, (n) December 31, 2015, upon payment to Landlord of Twelve and 03/100 Dollars ($12.03) per rentable square foot of terminated space, or (o) December 31, 2016, upon payment to Landlord of Ten and 62/100 Dollars ($10.62) per square foot of terminated space. If Tenant terminates less than all of the Quad III & IV Premises prior to June 30, 2014, then Tenant's right to exercise its remaining Quad III & IV Termination Options with respect to the portion of the Quad III & IV Premises not terminated shall survive until June 30, 2015 (i.e., eighteen (18) months prior to the last termination date). If Tenant receives any portion of the Phase 2 Quad III & IV Premises TI Allowance, then the payment required to terminate the Quad III & IV Premises shall increase by the unamortized portion of the Phase 2 Quad III & IV TI Allowance allocable to the terminated portion or portions of the Quad III & IV Premises as of the applicable termination date using straight-line amortization (such amortization period to commence as of the Swap Premises Rent Commencement Date). If Tenant timely exercises a Quad III & IV Termination Option, then Tenant shall (y) surrender the applicable Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration or earlier termination of the Term, and (z) if less than all of the Quad III & IV Premises are terminated by Tenant, demise the terminated Premises at its expense, such demising to be performed in accordance with Applicable Laws. Nothing in the foregoing clause (z) shall be deemed to require Tenant to perform any work to conform the terminated portion of the Premises with Applicable Laws (other than the demising thereof), except as may be expressly required by the Amended Lease.

b. Additionally, Tenant shall be entitled to terminate the Lease with respect to the entire Quad I & II Premises (the "Quad I & II Termination Option" and, together with the Quad III & IV Premises Termination Options, the "Swap Premises Termination Options") upon not less than eighteen (18) months' prior written notice to Landlord, effective as of (a) June 30, 2014, upon payment to Landlord of Twenty-Nine and 45/100s Dollars ($29.45) per rentable square foot of terminated space, (b) December 31, 2015, upon payment to Landlord of Twenty and 02/100s Dollars ($20.02) per rentable square foot of terminated space, or (c) December 31, 2016 upon payment to Landlord of Ten and 50/100s Dollars ($10.50) per square foot of terminated space.

14. Emisphere Lease; Regeneron Sublease.

a. Landlord represents and warrants that, as of the date hereof, Landlord and Emisphere have executed a lease termination agreement (the "Emisphere Termination Agreement") that terminated the Emisphere Lease, except for those provisions that, by their express terms, survive the expiration or earlier termination thereof. Landlord shall use commercially reasonable efforts to enforce any obligations of Emisphere under the Emisphere Termination Agreement to the extent necessary to deliver the Swap Premises to Tenant on the Swap Premises Commencement Date. In addition, Landlord agrees that it shall provide copies of any cleaning records, surveys, swipes or other reports that it obtains from Emisphere as a result of the Emisphere Termination Agreement regarding the presence of Hazardous Materials in the Swap Premises.

b. Landlord represents and warrants that, to its knowledge, as of the Execution Date, no Hazardous Materials exist in the Swap Premises in violation of Applicable Laws.

c. Tenant hereby represents and warrants to Landlord that, with respect to the Regeneron Sublease, (a) Tenant has not prepaid to Emisphere more than one (1) month's Rent, (b) Landlord shall have no liability for any security deposits or other amounts Tenant has paid to Emisphere, (c) Tenant shall look solely to Emisphere (not Landlord) for reimbursement of any prepaid Rent or return of any security deposit and (d) to its knowledge, there are no defaults, or conditions existing that with the passage of time may become a default, whether on behalf of Tenant or Emisphere.

15. Condition of Premises. Tenant acknowledges that (a) it is in possession of and is fully familiar with the condition of that portion of the Swap Premises occupied by Tenant pursuant to the Regeneron Sublease, (b) is familiar with the condition of the remainder of the Swap Premises and, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the Swap Premises in its condition "as is" as of the Swap Premises Commencement Date; provided, however, that Landlord shall deliver the Swap Premises (other than the Regeneron Sublease Premises) in broom clean condition, taking into account that Tenant has entered into a separate agreement with Emisphere to have those certain items of Emisphere's personal property set forth in the attached Exhibit C (the "Emisphere FF&E") remain in the Swap Premises after the termination of the Emisphere Lease. Landlord shall have no liability with respect to the Emisphere FF&E, except to the extent that the same form a part of the Buildings or the Common Areas and Landlord would otherwise be required to repair and maintain the same pursuant to Section 19.1 of the Amended Lease, in which case Landlord shall be obligated to fulfill such repair and maintenance obligations. For the avoidance of doubt, Landlord and Tenant agree that: (y) Landlord shall have no liability for the existence or condition of the Emisphere FF&E as of the Swap Premises Commencement Date and (z) the following items being left in the Swap Premises by Emisphere shall constitute and form a part of the Building: base building HVAC systems, elevators, restrooms, and exhaust fans and stacks.

16. Hazardous Materials. From and after the Swap Premises Commencement Date, the second to last sentence of Section 40.1 of the Lease shall be deleted and replaced in its entirety with the following:

> Landlord acknowledges that Tenant shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the Entire Project, in the New Whole Building, in the New Multiple Tenant Building, in the Retained Premises, in the Additional Premises or in the Swap Premises caused by Landlord or tenants other than Tenant or by third parties in the Entire Project prior to the Execution Date or after such date, or for environmental conditions or contamination coming from off-site so long as Tenant, Tenant's Affiliates, its permitted sublessees or its agents did not cause or contribute to such environmental conditions or contamination.

17. PsychoGenics License Agreement. Landlord and Tenant acknowledge that Tenant, as an accommodation to Landlord, intends to enter into a license agreement with PsychoGenics Inc. in substantially the form attached hereto as Exhibit D (the "PsychoGenics License Agreement"). Landlord, Tenant and PsychoGenics shall, prior to execution of the PsychoGenics License Agreement, enter into a consent to the PsychoGenics License Agreement on Landlord's customary form, a copy of which has been provided to Tenant prior to the date hereof.

18. Broker. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Studley ("Broker"), and each agrees to indemnify, defend and hold the other harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with this Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker, which commission shall be calculated on the rentable square footage of the Quad III & IV Premises only.

19. No Default; Authority; Non-Contravention. Each of Landlord and Tenant represents, warrants and covenants that, to the best of its respective knowledge, neither Landlord nor Tenant is in default of any of its respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both), would constitute a default by either Landlord or Tenant thereunder. Each of Landlord and Tenant further represents, warrants and covenants that it has the full power and authority to execute, deliver and comply with the terms of this Amendment, and doing so will not conflict with or result in the violation of or default under any provision of any agreement or other instrument to which it is a party (including without limitation, with respect to Landlord, the Emisphere Lease and the Emisphere Termination Agreement).

20. Effect of Amendment. Except as modified by this Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Amendment.

21. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference.

22. Counterparts. This Amendment may be executed in one or more counterparts that, when taken together, shall constitute one original.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Amendment.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By: /s/ Kevin M Simonsen
Name: Kevin M. Simonsen
Title: VP, Real Estate Counsel

TENANT:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

SWAP PREMISES

[DIAGRAM]

EXHIBIT B

SURRENDER PREMISES

[Diagram]

EXHIBIT C

EMISPHERE FF&E

Item	Qty.
VWR double-door refrigerator	1
Revco laboratory freezer	1
Fisher Scientific Isotemp Plus, double door	1
NuAire biological safety cabinet	2
Ice machine	1
Misc. stainless steel tables	14
Mobile benches	15
Bedding dump station	1
Narcotics safe	1
Flammable cabinets	10
Corrosive & acid cabinets	3
Cagewasher	1
Lab casework, incl. fume hoods	throughout
Cold room	1
Downdraft table	1
Animal watering system	1
Liebert air handling system in data center	1
Office furniture (not including chairs)	throughout

EXHIBIT D

FORM OF PSYCHOGENICS LICENSE AGREEMENT

LICENSE AGREEMENT

This LICENSE AGREEMENT (this "Agreement") is made as of this ___ day of April, 2009 (the "Effective Date") by and between REGENERON PHARMACEUTICALS, INC. ("Licensor") and PSYCHOGENICS INC. ("Licensee").

BACKGROUND

A. The Licensor is a tenant in the Building located at 765 Old Saw Mill River Road (the "Building"), located within the project the ("Project") known as The Landmark at Eastview, in the Towns of Mt. Pleasant and Greenburgh, New York. As tenant, Licensor has entered into a lease (as amended, supplemented or modified, the "Lease") with BMR-Landmark at Eastview, LLC (the "Landlord") for certain premises within the Project and, as of the Effective Date, is entering into an amendment of the Lease (the "Amendment") to lease from Landlord additional premises thereunder, comprising approximately 77,178 rentable square feet in the Building (the "Leased Premises").

B. Prior to the date hereof, Licensee occupied an approximately 2,275 rentable square foot portion of the Leased Premises as more precisely described and designated on Exhibit A attached hereto and made a part hereof (the "License Area") pursuant to a sublease (the "Sublease"), by and between Licensee, as subtenant and Emisphere Technologies Inc., as sublessor, which Sublease has been terminated as of the date hereof. Licensee desires to continue to occupy the License Area and, in furtherance thereof, to obtain a license from the Licensor for the temporary occupancy of the License Area. Licensor is willing to grant a license to Licensee, all subject to the terms and conditions set forth in this Agreement.

TERMS

NOW THEREFORE, in consideration of the mutual promises and agreements set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Licensor hereby grants to Licensee a license (the "License")to use the Licensed Area, subject to the following conditions:

1. License Area. Licensor hereby grants to Licensee a non-transferable right and revocable license for the temporary use of the License Area. Nothing in this Agreement shall be construed to create any relationship between the parties other than that of licensor and licensee.

2. Term. The term of the License (the "Term") shall commence on May 1, 2009 (the "Commencement Date") and shall expire on January 15, 2010, unless sooner terminated as provided in this Agreement (the "Expiration Date"). If Licensee remains in the License Area after the Expiration Date, then, in addition to all other remedies Licensor may have at law, in equity or under this Agreement, Licensee shall be deemed to be a licensee at sufferance only and the License Fee (as such term is defined in paragraph 4 below) shall be increased to two hundred percent (200%) of the License Fee (as such term is defined below). If Licensee fails to surrender and vacate the License Area upon the termination or expiration of this Agreement, then Licensee shall indemnify, defend and hold Licensor harmless from and against all loss and liability, including, without limitation, all costs to remove Licensee's personal property and any claims made by any succeeding licensee, subtenant, or any other occupant founded on or resulting from such failure to surrender or vacate, including, without limitation, any attorneys' fees, disbursements or other costs associated therewith.

3. Use. Licensee shall occupy and use the License Area during the term of this Agreement for the sole purposes of general, administrative, and executive use in rooms 721, 722 and 723, and laboratory use in Rooms 724, 726 and 727, and no other purpose without Licensor's prior written consent.

4. Fees.

A. Licensee shall pay to Licensor a monthly license fee of Eight Thousand, Six Hundred Twenty-Six and 40/100 Dollars ($8,626.40) (the "Fixed Fee"), provided that the following additional amounts shall also be due hereunder: (i) for the payment due on September 1, 2009 an additional amount equal to One Thousand, Two Hundred Sixty-Three and 35/100 Dollars ($1,263.35), and (ii) for the payment due on January 1, 2009, an additional amount equal to One Hundred Ninety-Seven and 12/100 Dollars ($197.12) (such additional amounts, together with the Fixed Fee, the "License Fee").

B. The License Fee for the month of May, 2009 shall be paid by Licensee on the date of the full execution of this Agreement, and thereafter, the License Fee shall be payable in advance on a monthly basis during the Term, on the first day of each month commencing on June 1, 2009, without notice, demand, set-off, claim, or counterclaim, by check or money order, made payable to Licensor at Licensor's address set forth below. If the first month or the last month of the Term shall be partial months, the License Fee for any such partial month shall be prorated on a daily basis.

5. Security Deposit. Licensee has deposited with Licensor a security deposit in the amount of Twenty Thousand Dollars ($20,000) (the "Security Deposit"), which sum shall be held by Licensor as security for the faithful performance by Licensee of all of the terms, covenants and conditions of this Agreement to be kept and performed by Licensee during the term. If Licensee defaults with respect to any provision of this Agreement, including, but not limited to, any provision relating to the payment of the License Fee, then Licensor may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any License Fees or any other sum in default, or to compensate Licensor for any other loss or damage that Licensor may suffer by reason of Licensee's default. If any portion of the Security Deposit is so used or applied, then Licensee shall, within ten (10) days following demand therefor, deposit cash with Licensor in an amount sufficient to restore the Security Deposit to its original amount, and Licensee's failure to do so shall be a material breach of this Agreement. Licensor shall not be required to keep this Security Deposit separate from its general funds, and Licensee shall not be entitled to interest on the Security Deposit. In the event of bankruptcy or other debtor-creditor proceedings against Licensee, the Security Deposit shall be deemed to be applied first to the payment of License Fee and other charges due Licensor for all periods prior to the filing of such proceedings. If Licensee shall fully and faithfully perform every provision of this Agreement to be performed by it, then the Security Deposit, or any balance thereof, shall be returned to Licensee within thirty (30) days after the expiration or earlier termination of this Agreement.

6. Late Charges. Late payment by Licensee to Licensor of the License Fee or any other sums due shall cause Licensor to incur costs not contemplated by this Agreement, the exact amount of which shall be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges that may be imposed on Licensor by the terms of its Lease. Therefore, if any installment of License Fee or other fees due from Licensee pursuant to this Agreement is not received by Licensor within five (5) days after the date such payment is due, Licensee shall pay to Licensor an additional sum of six percent (6%) of the overdue amount as a late charge. The parties agree that this late charge represents a fair and reasonable estimate of the costs that Licensor shall incur by reason of late payment by Licensee. In addition to the late charge, amounts not paid when due shall bear interest from the fifth (5th) day after the date due until paid at the lesser of (a) twelve percent (12%) per annum or (b) the maximum rate permitted by applicable laws.

7. Common Areas. Licensee shall have the right, subject to the provisions of this License, to use, without additional charge, on a non-exclusive basis, the common areas leased by Licensor pursuant to the Lease and the areas of the Leased Premises specified as "common areas" in the attached Exhibit A. Licensee shall be responsible for any and all damage caused by Licensee or its employees, agents and invitees in or to such common areas. Licensee shall not permit any of its files, furniture, personal property or other matters to be placed in such common areas, and shall keep such common areas free of debris and refuse. In addition to the foregoing, Licensee shall be entitled to access to the portion of the Leased Premises specified as "restricted access area" in the attached Exhibit A. Access to such restricted access areas shall be permitted only if (i) a representative of Licensor is present at all times during such access, and (ii) such access is solely for the purpose of allowing Licensee to use the elevator. Licensee agrees that it shall make available a representative for the purpose of such access during reasonable business hours and upon one (1) business days' advance notice, provided that Licensor shall use reasonable efforts (but shall not be obligated) to provide a representative on shorter notice, should exigent circumstances require the same.

8. Licensee's Maintenance; No Improvements. Licensee shall at all times maintain the License Area, and any equipment or property used or installed by Licensee in the License Area, in good, clean and safe condition, free of all debris and trash. Licensee shall not make any improvements, alterations or changes of any kind to the License Area without Licensor's prior written approval. In addition to all of Licensor's remedies under this Agreement, if (a) Licensee does not maintain the License Area as required under this Section or (b) repairs or replacement of any portion of the License Area is made necessary by any act, omission or negligence of Licensee or its agents, employees or invitees, then Licensor may make such repairs or provide such maintenance without liability to Licensee for any loss or damage to Licensee or its merchandise, fixtures or other property, or to Licensee's business by reason of such repairs or maintenance. Further, upon completion of any such repairs or maintenance, Licensee shall pay upon demand, as additional License Fee, one hundred percent of Licensor's costs for making such repairs or providing such maintenance, evidenced by invoices, together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of the total cost of such repair. Licensee shall not make any changes, alterations, installations, additions or improvements to the License Area without first obtaining the written consent of Licensor, which consent may be granted or withheld in the sole discretion of Licensor.

9. Hazardous Materials. Licensee shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept or used in or about the License Area, the Building or the Project in violation of Applicable Laws (as hereinafter defined) by Licensee, its agents, employees, contractors or invitees. If Licensee breaches such obligation, or if the presence of Hazardous Materials as a result of such a breach results in contamination of the License Area, the Leased Premises, the Building, the Project or any adjacent property, or if contamination of the License Area, the Leased Premises, the Building, the Project or any adjacent property by Hazardous Materials otherwise occurs during the Term or any extension or renewal hereof or holding over hereunder due to such breach by Licensee, then Licensee shall indemnify, save, defend and hold Licensor, its agents and contractors harmless from and against any and all losses, costs, damages or judgments (including sums paid in settlement, attorneys' fees, consultants' fees and experts' fees) that arise during or after the Term as a result of such breach or contamination. This indemnification of Licensor by Licensee includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, remedial, removal or restoration work required by any federal, state, regional, local or municipal governmental authority, agency or subdivision (collectively, the "Governmental Authorities") because of Hazardous Materials present in the air, soil or groundwater above, on or under the License Area, the Leased Premises, the Building, the Project or any adjacent property. Without limiting the foregoing, if the presence of any Hazardous Materials in, on, under or about the License Area, the Leased Premises, the Building, the Project or any adjacent property caused or permitted by Licensee results in any contamination of the License Area, the Leased Premises, the Building, the Project or any adjacent property, then Licensee shall promptly take all actions at its sole cost and expense as are necessary to return the License Area, the Leased Premises, the Building, the Project and any adjacent property to their respective condition existing prior to the time of such contamination; provided that Licensor's written approval and the written approval of Landlord of such action shall first be obtained, which approval Licensor shall not unreasonably withhold; and provided, further, that it shall be reasonable for Licensor to withhold its consent if (i) Landlord withholds such consent, or (ii) such actions could have a material adverse long-term or short-term effect on the License Area, the Leased Premises, the Building, the Project or any adjacent property. Licensor acknowledges that Licensee shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the License Area, the Leased Premises, the Building or the Project, or for environmental conditions or contamination coming from off site, to the extent the same was not caused or contributed to by Licensee, Licensee's affiliates, or their agents. Licensee's obligations under this paragraph shall survive the Expiration Date. During any period of time needed by Licensee or Licensor after the Expiration Date to complete the removal from the License Area of any such Hazardous Materials, Licensee shall continue to pay License Fee for the affected area(s) in accordance with this Agreement, which License Fee shall be pro-rated daily. As used herein, the term "Hazardous Material" means any hazardous or toxic substance, material or waste that is so designated by Applicable Laws and/or becomes regulated by any Governmental Authority.

10. Damage and Repairs. Any damage, destruction, graffiti or debris around, to, or on the License Area, the Leased Premises, the Building or the Project caused by Licensee, its agents, employees or invitees shall be Licensee's responsibility. If Licensee fails to repair, clean or replace any such damage or debris within two (2) days of Licensor's demand to do so, then Licensor may make such repairs, clean-up or replacement. Upon completion of any such repairs, clean-up or replacement, Licensee shall pay upon demand, as additional License Fee, one hundred percent (100%) of Licensor's costs for making such repairs or providing such clean-up or replacement, evidenced by invoices, together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal one twenty percent (20%) of the total cost of such repairs, clean-up or replacement. Any damage to the License Area caused directly by Licensor shall be Licensor's responsibility to repair and maintain.

11. Fire and Casualty Damage. If the License Area is rendered partially or wholly untenantable by fire or other casualty, this License shall terminate as to such affected License Area as of the date of such fire or casualty as if that date had been originally fixed in this Agreement for the Expiration Date for the affected License Area.

12. Transfer and Assignment. Licensee shall have no right to assign or transfer this License or rights arising under this License. Any assignment by operation of law or otherwise shall be deemed a prohibited assignment hereunder. In the event of a transfer or such assignment, this License shall automatically terminate and thereafter shall be considered null and void.

13. Inspections. Provided that Licensor uses reasonable efforts not to interfere with Licensee's use of the Licensed Area, Licensor shall have the right to enter the License Area at any reasonable time for the following purposes: (a) to ascertain the condition of the License Area; (b) to determine whether Licensee is diligently fulfilling Licensee's responsibilities under this License, or; (c) to do any other act or thing which Licensor deems reasonably necessary to preserve the Licensed Area or to comply with its obligations hereunder or under the Lease.

14. Termination of Agreement. On the Expiration Date, Licensee shall (a) return the License Area to Licensor in good, sanitary and satisfactory condition and (b) remove its equipment and any other of its property from the License Area, the Leased Premises, the Building and the Project, unless otherwise agreed to by Licensor. Licensee acknowledges and agrees that it shall reimburse Licensor upon demand for one hundred percent (100%) of Licensor's costs to repair any damage caused by such removal by Licensee, evidenced by invoices, together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of the total costs such repair. Any equipment or property not removed within two (2) days of the date of termination or expiration of this Agreement shall be deemed abandoned by Licensee, and Licensor shall have the right, but not the obligation, to remove and dispose of such abandoned equipment or property at Licensee's sole cost and risk, and Licensor shall be entitle to Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of the total costs such removal and disposal.

15. Personal Property Taxes. Licensee shall pay all sales and use taxes, if any, imposed as a result of Licensee's business conducted on the License Area and all taxes assessed against property of Licensee situated thereon during the Term.

16. Compliance with Laws; Liens. Licensee shall at all times observe and comply with all federal, state and local laws, ordinances, rules, regulations and code requirements (collectively, the "Applicable Laws"). Licensee shall obtain all permits and licenses for the operation of its business at the Building or its use or occupancy of the License Area and shall comply with all current and future rules and regulations of Landlord for tenants or licensees of the Leased Premises, the Building, or the Project. Licensee shall at all times maintain sufficient supervision and control of its employees and invitees. Licensee shall not (a) obstruct the free flow of pedestrian or vehicular traffic in any area of the Property, (b) harm the License Area, commit any waste, create a nuisance or make any use of the License Area that is offensive or (c) act or fail to act in any manner that could result in injury or harm to any person in or about the Property. Licensee shall, and shall instruct its employees, agents and invitees to, act in accordance with Landlord's rules and regulations as they may be promulgated by Landlord from time to time, provided Licensee is given copies thereof. Licensee shall keep the License Area free and clear of any mechanics' liens and other liens. Nothing in this Agreement shall be construed as consent on the part of Licensor to subject the Leased Premises, the Building or the Project to any lien or liability under the lien laws of the State of New York.

17. Insurance. Licensee shall, at all times during the Term, and at its own cost and expense, procure and continue in force insurance in the amounts and on the terms set forth in this Section 17. Said insurance shall name Landlord and Licensor as additional insureds and shall be subject to reasonable approval of Licensor and Landlord. Licensee shall obtain from the insurance companies, or cause the insurance companies to furnish, certificates of coverage. The delivery of proof of such insurance is a condition precedent to this Agreement. All certificates of insurance shall provide that the insurer will provide Licensor twenty (20) days notice of cancellation of or any change of said policies by certified mail, return receipt requested or via established overnight courier. In the event Licensee shall fail to comply with any or all of the provisions of this paragraph, Licensor is hereby authorized to purchase said insurance and charge Licensee for the premiums of same and any other costs incurred thereon, and such sums shall be deemed additional License Fee and may be collected by Licensor as such in the next ensuing installment of License Fee. At a minimum, Licensee shall procure Comprehensive General Liability Insurance, in the broadest form available in New York State, with a minimum amount of $3,000,000 combined single limit and which shall contain personal injury liability, fire damage liability on real property (with sublimits for such events in amounts no less than the minimum amount of $3,000,000), Workers Compensation Insurance, and such other insurance as was required pursuant to the Sublease.

Licensee agrees to use commercially reasonable efforts to include in each of its policies insuring against loss, damage or destruction by fire or other casualty, a waiver of the insurer's right of subrogation against Licensor. If such waiver shall not be, or shall cease to be, obtainable without additional charge, or is otherwise not available at all, Licensee shall promptly so notify Licensor. In such case, if the other party shall so elect and shall pay the insurer's additional charge therefore, such waiver shall be included in the policy.

18. Consent of Landlord. This Agreement is subject to the written consent of Landlord (the "Consent"), which consent shall be evidenced by Landlord's customary form of consent, with such changes as may be agreed to by the parties thereto. In the event Landlord rejects this Agreement, neither party shall have any rights against the other, and this Agreement shall be deemed null and void.

19. Utilities, Services. Licensor shall use commercially reasonable efforts to cause Landlord to furnish the License Area with all services required by the Lease to the extent Licensee was receiving the same pursuant to the Sublease. Licensor shall not be liable to Licensee for any loss, injury or damage to persons or property caused by or resulting from any variation, failure, or interruption of any services or utilities to be provided by Landlord under the Lease due to any cause whatsoever. Licensee's use or occupancy of the License Area shall not in any manner (i) cause the design loads for the Building or the systems providing exhaust, heating, cooling, ventilation, electrical, life safety, water, sewer or other utility or safety services to be exceeded or (ii) adversely affect the Building or the operation of said systems in the License Area, the Leased Premises or the Building or cause deterioration or damage to the Building or such systems.

20. Access and Parking. Licensee and its agents, employees and invitees may have access to the License Area during its above term twenty-four (24) hours a day. Licensee agrees that it shall not park in any reserved spot on the Property or in front of any roll access/loading doors to the other buildings. Licensee must also keep a fire lane available around the Building. Any costs or liability associated with enforcing this parking access shall be Licensee's or violator's sole responsibility.

21. Default. Any failure by Licensee to perform any term or condition of this Agreement shall constitute a default under this Agreement and, in such event, Licensor may exercise any remedy available to it under this Agreement, at law or in equity. Without limiting the foregoing, in the event any such default is not cured within forty-eight (48) hours of Licensor's notice to Licensee thereof, Licensor may, at its option, terminate this Agreement and revoke the license granted hereby. Licensee shall reimburse Licensor for any and all costs and expenses (including attorneys' fees and costs) that Licensor incurs in connection with enforcing Licensee's obligations under this Agreement.

22. Limitation of Recovery; Waiver. There shall be no personal liability of Licensor with respect to any of the terms of this Agreement. In the event of any breach or default by Licensor under this Agreement, Licensee shall look solely to the equity of Licensor in the Building for satisfaction of Licensee's remedies. Licensee releases and waives all right of recovery that it might otherwise have against Licensor, or other tenants or licensees of the Building, and their respective agents and employees, by reason of any loss or damage resulting from any recovery, claim, action or cause of action against Licensor, damage or injury or other occurrence no matter how caused, to the extent the same is either covered by Licensee's insurance (assuming no deductible) or would have been covered had Licensee complied with the requirements of this Agreement.

23. Entire Agreement. Other than Licensee's lease agreement with Licensor, this Agreement contains the entire agreement between the parties and all prior understandings and agreements between the parties are merged into this Agreement. This Agreement may be modified only by a writing signed by both of the parties hereto.

24. Acceptance of License Area. By taking possession of the License Area, Licensee shall be deemed to have inspected the License Area and accepted the License Area "as is" in its present condition. Licensee acknowledges and agrees that neither Licensor, nor any employee, agent nor representative of Licensor, has made any representation or warranty, express or implied, of any kind as to the condition of the License Area or its suitability for Licensee's proposed use. Licensee further acknowledges and agrees that Licensor has no obligation to improve, maintain or repair the License Area unless said obligation is expressly set forth in this Agreement.

25. Waiver of Responsibility; Indemnification. Licensee shall assume liability for, and shall indemnify, defend and hold harmless Licensor and its shareholders, members, officers, directors, employees, contractors, subcontractors, agents, customers, mortgagees, lenders and invitees from and against any and all liabilities, obligations, losses, fines, damages, claims, demands, judgments, penalties, expenses (including, without limitation, attorneys' fees and costs) arising, directly or indirectly, from (a) any labor dispute involving Licensee or its contractors or agents, (b) the use or enjoyment of the License Area or the Project by Licensee or its contractors, agents, employees and/or customers or invitees, (c) injury to or death of any person or persons, or damage to or destruction of any property (including, without limitation, the cost of investigation, removal or remedial action and disposal of any Hazardous Materials) occurring in, on or about the License Area or (d) a breach of this Agreement by Licensee or any act or omission of Licensee or its agents, employees or contractors ("Claims"). Notwithstanding anything to the contrary in this Section, nothing in this Section shall relieve Licensor from responsibility for its proportionate share of fault attributable to its negligence in causing any Claims. To the maximum extent permitted by law, Licensee's activities on and use of the License Area and the Property shall be at Licensee's sole risk. Licensee's obligations under this Section shall survive the Expiration Date.

26. Representations and Warranties.

A. Licensee represents and warrants to Licensor that, as of the Effective Date, the Sublease has been terminated and Licensee waives all rights of possession and occupancy of any portion of the Leased Premises pursuant thereto.

27. Licensor hereby represents and warrants to Licensee that (i) as of the Effective Date, the Lease and the Amendment are in full force and effect and grant to Licensor a leasehold interest in and to the Leased Premises, and (ii) the Amendment does not materially modify the Lease with respect to Licensee's obligations under the Consent. Licensor shall provide Licensee with a fully-executed copy of the Amendment within five (5) business days of the date on which the same is made a part of the public record.

28. Signage. Licensee is responsible for all of Licensee's signage. All signage must be pre-approved in writing by Licensor and Landlord and hand-written signs are not permitted.

29. Miscellaneous.

A. Whenever under this License Agreement provision is made for any demand, notice, requests or declaration of any kind, or where it is deemed desirable or necessary by either party to give or serve any such notice, demand, request or declaration to the other party, it shall be in writing and such notices shall be deemed given when personally delivered, or the next business day after delivery to a reputable overnight delivery service such as Federal Express or United Parcel Service to the following addresses:

To the Licensor at:

REGENERON PHARMACEUTICALS, INC.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attn: General Counsel

with copy to:

REGENERON PHARMACEUTICALS, INC.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attn: Joanne Deyo, Vice President Facilities

To Licensee at:

PSYCHOGENICS INC.
765 Old Saw Mill River Road
Tarrytown, New York 10591
Attn: William Fasnacht, CFO/COO

B. The terms, provisions and covenants and conditions contained in this License shall apply to, inure to the benefit of, and be binding upon, the parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns.

C. All obligations of Licensee hereunder not fully performed as of the Expiration Date shall survive the Expiration Date.

D. Licensor and Licensee agree to indemnify the other for any claims made by any other brokers arising under the acts of such party.

E. Licensee represents that it has used no broker in connection with this transaction.

F. This Agreement may be signed in counterparts; each, when taken together, shall constitute one instrument.

G. If any term, provision or condition of this License shall, to any extent, be finally adjudicated to be invalid or unenforceable, the remainder of this License (or the application of such term, provision or condition to persons or circumstances other than those in respect of which it is finally adjudicated to be invalid or unenforceable) shall not be affected thereby and each and every other term, provision and condition of this License shall be valid and enforceable to the fullest extent permitted by law.

H. Licensee shall pay to Licensor all costs and expenses, including reasonable attorneys' fees and costs, incurred by Licensor in connection with any action between Licensor and Licensee arising out of this License or incurred by Licensor as a result of any litigation to which Licensor becomes a party as a result of this License or Licensee's use and occupancy of the Licensed Area or any portion thereof.

I. Licensor and Licensee waive trial by jury in the event of any action, proceeding or counterclaim brought by either Licensor or Licensee against the other in connection with this License.

J. If Licensee fails timely to perform any of its duties under this License, Licensor shall have the right (but not the obligation), after the expiration of any grace or notice and cure period elsewhere under this License expressly granted to Licensee for the performance of such duty, to perform such duty on behalf and at the expense of Licensee (but only upon prior notice to Licensee), and all sums expended or expenses incurred by Licensor in performing such duty together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of Licensor's cost of performing such duty, shall be deemed to be additional License Fee under this License and shall be due and payable upon demand by Licensor.

K. This Agreement shall be governed by, and construed and interpreted in accordance with New York law, without regard to conflicts of law principles.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Licensor and Licensee have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Agreement.

LICENSOR:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By: _____
Name: Murray A. Goldberg
Title: Senior Vice President,
Finance & Administration
and Chief Financial Officer

LICENSEE:

PSYCHOGENICS INC.,
a Delaware corporation

By: _____
Name: William Fasnacht
Title: CFO/COO

EXHIBIT A

LICENSE AREA

[Diagram]

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2009

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2009

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
April 30, 2009

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
April 30, 2009

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 11/3/2009

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2009

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No __

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes __ No __

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer __
Non-accelerated filer ___ (Do not check if a smaller reporting company) Smaller reporting company __

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes __ No X

Number of shares outstanding of each of the registrant's classes of common stock as of October 15, 2009:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,246,698

Common Stock, $0.001 par value	78,247,674

REGENERON PHARMACEUTICALS, INC.
Table of Contents
September 30, 2009

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at September 30, 2009 and December 31, 2008	3
	Condensed statements of operations (unaudited) for the three and nine months ended September 30, 2009 and 2008	4
	Condensed statement of stockholders' equity (unaudited) for the nine months ended September 30, 2009	5
	Condensed statements of cash flows (unaudited) for the nine months ended September 30, 2009 and 2008	6
	Notes to condensed financial statements (unaudited)	7-17
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	18-42
Item 3	Quantitative and Qualitative Disclosures About Market Risk	43
Item 4	Controls and Procedures	43
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	43
Item 1A	Risk Factors	44-59
Item 6	Exhibits	59
SIGNATURE PAGE		60

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2009 AND DECEMBER 31, 2008 (Unaudited)
(In thousands, except share data)

	September 30, 2009	December 31, 2008 (Revised - see Note 9)
ASSETS		
Current assets		
Cash and cash equivalents	$ 250,321	$ 247,796
Marketable securities	129,475	226,954
Accounts receivable from the sanofi-aventis Group	63,953	33,302
Accounts receivable - other	3,813	1,910
Prepaid expenses and other current assets	14,032	11,480
Total current assets	461,594	521,442
Restricted cash	1,600	1,650
Marketable securities	57,200	51,061
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	215,169	142,035
Other assets	6,629	8,032
Total assets	$ 742,192	$ 724,220
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 55,291	$ 36,168
Deferred revenue from sanofi-aventis, current portion	21,580	21,390
Deferred revenue - other, current portion	37,294	26,114
Total current liabilities	114,165	83,672
Deferred revenue from sanofi-aventis	90,251	105,586
Deferred revenue - other	49,421	56,835
Facility lease obligation	62,571	54,182
Other long-term liabilities	3,341	2,431
Total liabilities	319,749	302,706
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, $.001 par value, 40,000,000 shares authorized; shares issued and outstanding - 2,246,698 in 2009 and 2,248,698 in 2008	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 78,243,286 in 2009 and 77,642,203 in 2008	78	78
Additional paid-in capital	1,323,432	1,294,813
Accumulated deficit	(904,606)	(873,265)
Accumulated other comprehensive income (loss)	3,537	(114)
Total stockholders' equity	422,443	421,514
Total liabilities and stockholders' equity	$ 742,192	$ 724,220

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
		(Revised - see Note 9)		*(Revised - see Note 9)*
Revenues				
Contract research and development from sanofi-aventis	$ 68,536	$ 42,006	$ 178,928	$ 116,346
Other contract research and development	13,946	10,872	40,176	33,568
Research progress payments	20,000		20,000	
Technology licensing	10,000	10,000	30,000	30,000
Net product sales	4,973	2,706	13,364	2,706
	117,455	65,584	282,468	182,620
Expenses				
Research and development	105,434	72,089	279,972	200,335
Selling, general, and administrative	12,840	11,103	35,892	35,652
Cost of goods sold	472	292	1,299	292
	118,746	83,484	317,163	236,279
Loss from operations	(1,291)	(17,900)	(34,695)	(53,659)
Other income (expense)				
Investment income	857	3,674	3,935	15,513
Interest expense	(581)	(1,772)	(581)	(7,457)
Loss on early extinguishment of debt		(7)		(938)
	276	1,895	3,354	7,118
Net loss before income tax expense	(1,015)	(16,005)	(31,341)	(46,541)
Income tax expense		3,079		3,079
Net loss	$ (1,015)	$ (19,084)	$ (31,341)	$ (49,620)
Net loss per share, basic and diluted	$ (0.01)	$ (0.24)	$ (0.39)	$ (0.63)
Weighted average shares outstanding, basic and diluted	79,866	78,937	79,663	78,706

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)
For the nine months ended September 30, 2009
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2008 *(Revised see Note 9)*	2,249	$ 2	77,642	$ 78	$ 1,294,813	$ (873,265)	$ (114)	$ 421,514	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			518		4,626			4,626	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,491			1,491	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock-based compensation expense					22,802			22,802	
Net loss						(31,341)		(31,341)	$ (31,341)
Change in net unrealized gain (loss) on marketable securities							3,651	3,651	3,651
Balance, September 30, 2009	2,247	$ 2	78,243	$ 78	$ 1,323,432	$ (904,606)	$ 3,537	$ 422,443	$ (27,690)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30,	
	2009	2008 *(Revised - see Note 9)*
Cash flows from operating activities		
Net loss	$ (31,341)	$ (49,620)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	9,312	8,661
Non-cash compensation expense	22,602	24,716
Loss on early extinguishment of debt		938
Net realized (gain) loss on marketable securities	(56)	1,166
Changes in assets and liabilities		
Increase in accounts receivable	(32,554)	(23,886)
Increase in prepaid expenses and other assets	(370)	(5,279)
Decrease in deferred revenue	(11,379)	(10,076)
Increase in accounts payable, accrued expenses, and other liabilities	17,960	134
Total adjustments	5,515	(3,626)
Net cash used in operating activities	(25,826)	(53,246)
Cash flows from investing activities		
Purchases of marketable securities	(190,666)	(478,276)
Sales or maturities of marketable securities	284,934	443,587
Capital expenditures	(75,002)	(19,117)
Decrease (increase) in restricted cash	50	(50)
Net cash provided by (used in) investing activities	19,316	(53,856)
Cash flows from financing activities		
Extinguishment of long-term debt		(83,304)
Proceeds in connection with facility lease obligation	5,182	
Payments in connection with facility lease obligation	(773)	
Net proceeds from the issuance of Common Stock	4,626	6,165
Net cash provided by (used in) financing activities	9,035	(77,139)
Net increase (decrease) in cash and cash equivalents	2,525	(184,241)
Cash and cash equivalents at beginning of period	247,796	498,925
Cash and cash equivalents at end of period	$ 250,321	$ 314,684

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2008 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. In addition, the previously issued balance sheet of the Company at December 31, 2008 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, and the previously issued condensed statement of operations for the three and nine months ended September 30, 2008 and condensed statement of cash flows for the nine months ended September 30, 2008, contained in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2008, have been revised in this Quarterly Report on Form 10-Q with respect to the Company's December 2006 lease of office and laboratory facilities in Tarrytown, New York by applying authoritative guidance issued by the Financial Accounting Standards Board (FASB). See Note 9b below.

Included in research and development expenses is the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare LLC, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. The Bayer HealthCare estimate each quarter is adjusted to agree with actual expenses for such quarter in the subsequent interim fiscal quarter.

Effective in the first quarter of 2009, the estimated useful lives of laboratory and other equipment, which is a component of property, plant, and equipment, has been extended from 3 – 5 years to 3 – 10 years. The effect of this change in estimate was to lower depreciation expense by $0.2 million and $0.7 million for the three and nine months ended September 30, 2009. The impact on the net loss per share as a result of this change in estimate was not material.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company recognizes ARCALYST net product sales as revenue when the right of return no longer exists and rebates can be reasonably estimated. ARCALYST net product sales revenue totaled $5.0 million and $13.4 million for the three and nine months ended September 30, 2009, respectively, and $2.7 million for both the three and nine months ended September 30, 2008. At September 30, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $5.0 million and $3.8 million, respectively.

Cost of goods sold related to ARCALYST sales, which consisted primarily of royalties, totaled $0.5 million and $1.3 million for the three and nine months ended September 30, 2009, respectively, and $0.3 million for both the three and nine months ended September 30, 2008. To date, ARCALYST shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At September 30, 2009, the Company had $0.4 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and nine months ended September 30, 2009 and 2008, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2009	2008
Net loss (Numerator)	$ (1,015)	$ (19,084)
Weighted-average shares, in thousands (Denominator)	79,866	78,937
Basic and diluted net loss per share	$ (0.01)	$ (0.24)

	Nine Months Ended September 30,	
	2009	2008
Net loss (Numerator)	$ (31,341)	$ (49,620)
Weighted-average shares, in thousands (Denominator)	79,663	78,706
Basic and diluted net loss per share	$ (0.39)	$ (0.63)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the September 30, 2009 and 2008 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2009	2008
Stock Options:		
Weighted average number, in thousands	19,860	17,454
Weighted average exercise price	$ 17.65	$ 17.31
Restricted Stock:		
Weighted average number, in thousands	500	500
Convertible Debt:		
Weighted average number, in thousands		3,890
Conversion price		$ 30.25

	Nine months ended September 30,	
	2009	2008
Stock Options:		
Weighted average number, in thousands	20,059	17,572
Weighted average exercise price	$ 17.59	$ 17.24
Restricted Stock:		
Weighted average number, in thousands	500	500
Convertible Debt:		
Weighted average number, in thousands		5,450
Conversion price		$ 30.25

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2009 and December 31, 2008 were $10.5 million and $7.0 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2008 and December 31, 2007 were $5.1 million and $1.7 million, respectively, of accrued capital expenditures.

In connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 9b), the Company recognized a facility lease obligation of $4.0 million and $23.0 million for the nine months ended September 30, 2009 and 2008, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in accounts payable and accrued expenses at December 31, 2008 and 2007 were $1.5 million and $1.1 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2009 and 2008, the Company contributed 81,086 and 58,575 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2009 and December 31, 2008 were $1.0 million and $1.7 million, respectively, of accrued interest income. Included in marketable securities at both September 30, 2008 and December 31, 2007 was $2.2 million of accrued interest income.

5. Marketable Securities

Marketable securities at September 30, 2009 and December 31, 2008 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $7.1 million and $3.7 million at September 30, 2009 and December 31, 2008, respectively, and the aggregate cost basis of which was $4.0 million and $4.1 million at September 30, 2009 and December 31, 2008. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at September 30, 2009 and December 31, 2008. The Company classifies its debt securities, other than mortgage-backed and other asset-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed and other asset-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair	Unrealized		
At September 30, 2009	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	$ 105,253	$105,353	$ 100		$ 100
Corporate bonds	15,819	16,109	290		290
Mortgage-backed securities	3,417	3,211		$ (206)	(206)
U.S. government guaranteed collateralized mortgage obligations	4,717	4,802	85		85
	129,206	129,475	475	(206)	269
Maturities between one and three years					
U.S. government guaranteed corporate bonds	48,608	49,086	478		478
Mortgage-backed securities	1,278	999		(279)	(279)
	49,886	50,085	478	(279)	199
	$ 179,092	$179,560	$ 953	$ (485)	$ 468

At December 31, 2008	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Maturities within one year					
U.S. government obligations	$ 170,993	$172,253	$1,260		$1,260
Corporate bonds	26,894	26,662	25	$ (257)	(232)
Mortgage-backed securities	9,098	8,420		(678)	(678)
Other asset-backed securities	7,842	7,829		(13)	(13)
U.S. government guaranteed collateralized mortgage obligations	11,742	11,792	50		50
	226,569	226,956	1,335	(948)	387
Maturities between one and three years					
U.S. government guaranteed corporate bonds	29,853	29,811	82	(124)	(42)
Corporate bonds	10,446	10,414	77	(109)	(32)
Mortgage-backed securities	1,821	1,556		(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	5,297	5,570	273		273
	47,417	47,351	432	(498)	(66)
	$ 273,986	$274,307	$1,767	$(1,446)	$ 321

At September 30, 2009 and December 31, 2008, marketable securities included an additional unrealized gain of $3.1 million and an additional unrealized loss of $0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at September 30, 2009 and December 31, 2008. The debt securities listed at September 30, 2009 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
At September 30, 2009	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Mortgage-backed securities			$ 4,210	$ (485)	$ 4,210	$ (485)
At December 31, 2008						
Corporate bonds	$ 15,559	$ (287)	$ 2,933	$ (79)	$ 18,492	$ (366)
Government guaranteed corporate bonds	11,300	(124)			11,300	(124)
Mortgage-backed securities	871	(74)	9,104	(869)	9,975	(943)
Other asset-backed securities	7,829	(13)			7,829	(13)
Equity securities	3,608	(436)			3,608	(436)
	$ 39,167	$ (934)	$ 12,037	$ (948)	$ 51,204	$ (1,882)

Realized gains and losses are included as a component of investment income. For both the three and nine months ended September 30, 2009, realized gains on sales of marketable securities totaled $0.2 million and realized losses on sales of marketable securities were not significant. For the three and nine months ended September 30, 2008, realized gains on sales of marketable securities totaled $1.0 million and $1.1 million, respectively, and realized losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at September 30, 2009 and December 31, 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
Description	Fair Value at September 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities				
U.S. government obligations	$ 105,353		$ 105,353	
U.S. government guaranteed corporate bonds	49,086		49,086	
Corporate bonds	16,109		16,109	
Mortgage-backed securities	4,210		4,210	
U.S. government guaranteed collateralized mortgage obligations	4,802		4,802	
Equity securities	7,115	7,115		
Total	$ 186,675	$ 7,115	$ 179,560	$

		Fair Value Measurements at Reporting Date Using		
Description	Fair Value at December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities				
U.S. government obligations	$ 172,253		$ 172,253	
U.S. government guaranteed corporate bonds	29,811		29,811	
Corporate bonds	37,076		37,076	
Mortgage-backed securities	9,976		9,976	
Other asset backed securities	7,829		7,829	
U.S. government guaranteed collateralized mortgage obligations	17,362		17,362	
Equity securities	3,708	$ 3,608		$ 100
Total	$ 278,015	$ 3,608	$ 274,307	$ 100

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the best price for these securities. During the three and nine months ended September 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities. During the third quarter of 2008, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the security's $2.0 million carrying value. As a result, the Company recognized a $1.7 million charge related to this Level 2 marketable security, which the Company considered to be other than temporarily impaired.

Marketable securities included in Level 3 were valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the nine months ended September 30, 2009 and 2008, deterioration in the credit quality of a marketable security included in Level 3 subjected the Company to the risk of not being able to recover the carrying value of the investment. As such, the Company recorded charges for other-than-temporary impairment of this Level 3 marketable security totaling $0.1 million for both the three and nine months ended September 30, 2009, and $0.5 million for the nine months ended September 30, 2008.

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the three or nine months ended September 30, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the three and nine months ended September 30, 2009 and 2008.

Changes in marketable securities included in Level 3 during the three months ended September 30, 2009 and 2008 were as follows:

	Level 3 marketable securities	
	2009	2008
Balance, July 1	$ 100	$ 4,995
Settlements		(5,665)
Realized gain		940
Impairments	(100)	
Balance, September 30	$	$ 270

Changes in marketable securities included in Level 3 during the nine months ended September 30, 2009 and 2008 were as follows:

	Level 3 marketable securities	
	2009	2008
Balance, January 1	$ 100	$ 7,950
Settlements		(8,090)
Realized gain		940
Impairments	(100)	(530)
Balance, September 30	$	$ 270

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2009 and December 31, 2008 consist of the following:

	September 30, 2009	December 31, 2008
Accounts payable	$ 13,855	$ 6,268
Payable to Bayer HealthCare	2,753	9,799
Accrued payroll and related costs	15,706	5,948
Accrued clinical trial expense	11,637	4,273
Accrued property, plant, and equipment expenses	5,838	5,994
Accrued expenses, other	5,502	3,886
	$ 55,291	$ 36,168

7. Research Progress Payment from Bayer HealthCare LLC

In connection with the Company's license and collaboration agreement with Bayer HealthCare LLC to globally develop and commercialize outside the United States the Company's VEGF Trap-Eye for the treatment of eye disease by local administration, the Company received a $20.0 million substantive milestone payment in July 2009 in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in Central Retinal Vein Occlusion ("CRVO"). The $20.0 million payment was recognized in revenues as a research progress payment for the three and nine months ended September 30, 2009.

8. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. For the three and nine months ended September 30, 2009 and 2008, the components of comprehensive loss are:

	Three months ended September 30,	
	2009	2008
Net loss	$ (1,015)	$ (19,084)
Change in net unrealized gain (loss) on marketable securities	2,523	(3,645)
Total comprehensive income (loss)	$ 1,508	$ (22,729)

	Nine months ended September 30,	
	2009	2008
Net loss	$ (31,341)	$ (49,620)
Change in net unrealized gain (loss) on marketable securities	3,651	(4,130)
Total comprehensive loss	$ (27,690)	$ (53,750)

9. Lease – Tarrytown, New York Facilities

a. Lease Amendment

The Company leases laboratory and office facilities in Tarrytown, New York. In December 2006, the Company entered into an agreement (which was amended in October 2007 and September 2008) to lease laboratory and office space at the Company's Tarrytown location, including newly constructed space that was completed during the third quarter of 2009 (the "new facilities"). The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, the Company amended the lease agreement to increase the amount of space the Company will lease. As amended, the lease contains early termination options for the portion of the space that excludes the new facilities. Other terms and conditions, as previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, the Company terminated an April 2008 sublease for space in Tarrytown, New York.

In connection with the April 2009 lease amendment, the Company's total estimated future minimum noncancelable lease commitments, previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, will increase to $9.4 million, $14.5 million, $14.7 million, $13.7 million, and $15.1 million for the years ended December 31, 2009, 2010, 2011, 2012, and 2013, respectively, and increase to an aggregate amount of $182.5 million for the eleven-year period commencing on January 1, 2014.

b. Revisions of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, the Company became aware that certain of these conditions were applicable to its December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

The Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities. In addition, the Company's statement of cash flows for the quarter ended March 31, 2009 was revised to reclassify, from an operating activity to a financing activity, a $5.2 million reimbursement received from the Company's landlord for tenant improvement costs that the Company incurred. Under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation.

As previously disclosed, the above described revisions consisted entirely of non-cash adjustments. They had no impact on the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the preclinical and clinical development of its product candidates. The revisions also had no impact on the Company's previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009 (as described above), had no impact on the Company's previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on the Company's previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, the Company determined that the judgment of a reasonable person relying on the Company's previously issued financial statements would not have been changed or influenced by these revisions.

Balance Sheet Impact at December 31, 2007 and 2008, and March 31, 2009
(in millions)

For comparative purposes, the impact of the above described revisions to the Company's balance sheets as of the dates set forth below is as follows:

	December 31, 2007	December 31, 2008	March 31, 2009
As originally reported			
Property, plant, and equipment, net	$ 58.3	$ 87.9	$ 109.8
Total assets	936.3	670.0	681.4
Other long-term liabilities		5.1	13.2
Total liabilities	476.0	251.2	271.1
Accumulated deficit	(793.2)	(875.9)	(893.4)
Total stockholders' equity	460.3	418.8	410.3
Total liabilities and stockholders' equity	936.3	670.0	681.4
As revised			
Property, plant, and equipment, net	$ 79.9	$ 142.0	$ 164.6
Total assets	957.9	724.2	736.2
Facility lease obligation	21.6	54.2	60.0
Other long-term liabilities	0.9	2.4	3.2
Total liabilities	498.5	302.7	321.1
Accumulated deficit	(794.1)	(873.3)	(888.7)
Total stockholders' equity	459.4	421.5	415.1
Total liabilities and stockholders' equity	957.9	724.2	736.2

For comparative purposes, the impact of the above described revisions to the Company's statements of operations and statement of cash flows for the period(s) set forth below is as follows:

Statements of Operations Impact for the three, six, and nine month periods ended March 31, June 30, and September 30, 2008, the years ended December 31, 2007 and 2008, and the three months ended March 31, 2009
(in millions, except per share data)

	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2007	December 31, 2008	March 31, 2009
As originally reported						
Research and development expenses	$ 61.3	$ 127.8	$ 201.7	$ 201.6	$278.0	$ 82.1
Selling, general, and administrative expenses	11.0	24.5	35.9	37.9	49.3	11.7
Total expenses	72.3	152.3	237.9	239.5	328.3	94.2
Net loss	(11.6)	(30.1)	(51.2)	(105.6)	(82.7)	(17.5)
Net loss per share, basic and diluted	$ (0.15)	$ (0.38)	$ (0.65)	$ (1.59)	$ (1.05)	$ (0.22)
As revised						
Research and development expenses	$ 61.5	$ 128.2	$ 200.3	$ 202.5	$274.9	$ 80.3
Selling, general, and administrative expenses	11.1	24.6	35.7	37.9	48.9	11.4
Total expenses	72.5	152.8	236.3	240.4	324.7	92.1
Net loss	(11.8)	(30.5)	(49.6)	(106.5)	(79.1)	(15.4)
Net loss per share, basic and diluted	$ (0.15)	$ (0.39)	$ (0.63)	$ (1.61)	$ (1.00)	$ (0.19)

Statement of Cash Flows Impact for the three months ended March 31, 2009
(in millions)

	As Originally Reported	As Revised
Net cash used in operating activities	$ (10.2)	$ (15.4)
Net cash used in investing activities	(39.5)	(39.5)
Net cash provided by financing activities	1.0	6.2
Net decrease in cash and cash equivalents	$ (48.7)	$ (48.7)

These revised amounts, as applicable, are reflected in the Company's financial statements included in this Quarterly Report on Form 10-Q for the period ended September 30, 2009, and will be reflected in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 and the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2010.

c. Facility Lease Obligation

As described above in Note 9b, in connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities constructed in Tarrytown, New York by the Company's landlord, the Company capitalized the landlord's costs of constructing the new facilities, which totaled $58.2 million as of September 30, 2009, and recognized a corresponding facility lease obligation of $58.2 million. The Company also recognized, as an additional facility lease obligation, a $5.2 million reimbursement received from the Company's landlord for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service by the Company in September 2009. For the three and nine months ended September 30, 2009, the Company recognized $0.6 million of interest expense in connection with the facility lease obligation in the Company's statement of operations. At September 30, 2009, the facility lease obligation balance was $62.6 million.

10. Royalty Agreements with Novartis Pharma AG

In June 2009, the Company entered into two royalty agreements with Novartis Pharma AG ("Novartis") that replaced a previous collaboration and license agreement. Under the first royalty agreement, the Company is entitled to receive royalties on worldwide sales of Novartis' canakinumab (ACZ885), a fully human anti-interleukin-IL1ß antibody approved to treat CAPS and in development for a number of other inflammatory diseases. On the basis of the same agreement, the Company waived its rights to opt-in to the development and commercialization of canakinumab. Under the second royalty agreement, Novartis is entitled to receive royalties on worldwide sales of a second-generation interleukin-1 Trap, should the Company decide to proceed in the development of, and ultimately commercialize, this Trap. The financial terms of both agreements are identical in relation to stepped royalties to be paid on the basis of future sales, which start at 4% and reach 15% when annual sales exceed $1.5 billion. The agreements do not provide for any upfront or milestone payments or any sharing of development expenses.

The royalty agreements replace a 2003 collaboration and license agreement under which the Company had the right to opt in to the development and commercialization of Novartis' interleukin-1 antibody and Novartis had the right to opt in to the development and commercialization of the Company's second-generation interleukin-1 Trap. That collaboration and license agreement has been terminated.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

12. Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement by requiring the use of estimated selling price to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company will be required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management is currently evaluating the impact that this guidance will have on the Company's financial statements.

13. Subsequent Events

The Company has evaluated subsequent events through November 3, 2009, the date on which the financial statements were issued, and has determined that there are no subsequent events that require adjustments to the financial statements for the quarter ended September 30, 2009.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We also have six product candidates currently in clinical development, including three in late-stage clinical development. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST, which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our clinical development and manufacturing capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*VelocImmune®*) and cell line expression technologies (*VelociMab™*) may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using *VelocImmune*. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) – Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped $5.3 million and $15.0 million of ARCALYST to our distributors during the third quarter and first nine months of 2009, respectively, compared to $4.3 million and $6.7 million in the same periods of 2008. We expect to ship approximately $20 million of ARCALYST to our U.S. distributors in 2009, compared to $10.7 million in 2008.

In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMEA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older. Such authorizations are permissible for products for which a company can demonstrate that comprehensive data cannot be provided, for example, because of the rarity of the condition. Each year, we will need to provide for review by the EMEA any new or follow-up information that may become available. We own worldwide rights to ARCALYST (rilonacept).

ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

Clinical Programs:

1. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF), VEGF-B and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, VEGF-B and PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in three Phase 3 trials that are evaluating combinations of aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. At the end of the third quarter of 2009, each of these trials was more than 80% enrolled. Analyses of the data from these studies will be conducted when a prespecified number of events have occurred in each trial. Based on current enrollment and event rates, an interim analysis of the Phase 3 study in colorectal cancer is expected to be conducted by an Independent Data Monitoring Committee (IDMC) in the second half of 2010. Complete results from this study in colorectal cancer and from the study in non-small cell lung cancer are anticipated in the first half of 2011. Based on current enrollment and event rates, an interim analysis of the prostate study is expected to be conducted by an IDMC in mid-2011, with complete results anticipated in 2012. In addition, we and sanofi-aventis are conducting a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin.

In September 2009, as previously reported, a fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC. As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported on the combination arm with aflibercept were generally as anticipated.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) collaborate on the development and commercialization of aflibercept globally. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also are conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare also initiated a Phase 3 program in Central Retinal Vein Occlusion (CRVO) in July 2009. In connection with the dosing of the first patient in a Phase 3 study in CRVO, we received a $20.0 million milestone payment from Bayer HealthCare.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), marketed by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 are now fully enrolled, and initial data are expected in late 2010.

We and Bayer HealthCare have conducted a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. These one-year study results were reported at the 2008 annual meeting of the Retina Society. In this double-masked Phase 2 trial, known as CLEAR-IT 2, 157 patients were initially treated for three months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial three-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters ($p<0.0001$ versus baseline) and 5.4 letters ($p<0.085$ versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns ($p<0.0001$ versus baseline) and 125 microns ($p<0.0001$ versus baseline) at week 52, respectively. After week 12 to week 52 in the PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Twenty-four-month results of the extension stage were presented in October 2009 at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters ($p<0.0001$ versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters ($p<0.0001$ versus baseline) at one year, and 6.1 letters ($p<0.0001$ versus baseline) at month 12 of the extension stage. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study began in December 2008 and completed enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia in July 2009. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24. These data are expected to be reported during the first half of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of Central Retinal Vein Occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. Enrollment in the COPERNICUS study began during the third quarter of 2009, and enrollment in the GALILEO study began in October 2009. Initial data are anticipated in early 2011.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of $75.0 million from Bayer HealthCare. In 2007, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in CRVO. We can earn up to $70 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. ARCALYST® (rilonacept) – Inflammatory Diseases

We are evaluating ARCALYST in gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

Results from this study after the first 16 weeks of urate-lowering therapy were reported at the annual meeting of the European League Against Rheumatism (EULAR) in June 2009. Through 16 weeks, the mean number of flares per patient was 0.93 with placebo and 0.22 with ARCALYST (p=0.0036). In the first 16 weeks of treatment, 47.6% of patients treated with placebo experienced a gout flare and, of those, 55.0% had more than one flare. Among patients treated with ARCALYST, 22.0% experienced a gout flare (p=0.0209 versus placebo) and none had more than one flare. Adverse events after 16 weeks of treatment were similar to those reported after 12 weeks with the most frequently reported categories being infection and musculoskeletal complaints.

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, all of which are currently enrolling patients. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE). We expect to report initial data from the Phase 3 program during the first half of 2010.

In June 2009, we announced that we had entered into two royalty agreements with Novartis Pharma AG that replaced a previous collaboration and license agreement. Under the first royalty agreement, we are entitled to receive royalties on worldwide sales of Novartis' canakinumab (ACZ885), a fully human anti-interleukin-IL1ß antibody. Under this agreement, we also waived our rights to opt-in to the development and commercialization of canakinumab. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for chronic gout and a number of other inflammatory diseases. On October 20, 2009, Novartis announced positive Phase 2 results showing that canakinumab is significantly more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout.

Under the second royalty agreement, Novartis is entitled to receive royalties on worldwide sales of a second-generation interleukin-1 Trap, should we decide to proceed in the development of this Trap. The financial terms of both agreements are identical in relation to stepped royalties, to be paid on the basis of future sales, which start at 4% and reach 15%, when annual sales exceed $1.5 billion. The agreements do not provide for any upfront or milestone payments or any sharing of development expenses.

The royalty agreements replace a 2003 collaboration and license agreement under which we had the right to opt in to the development and commercialization of Novartis' interleukin-1 antibody and Novartis had the right to opt in to the development and commercialization of our second-generation interleukin-1 Trap. That collaboration and license agreement has been terminated.

4. Monoclonal Antibodies

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune®* technology. The first therapeutic antibody product candidates to enter clinical development under the collaboration are REGN88, REGN475, and REGN421. During the third quarter of 2009, REGN475, an antibody to Nerve Growth Factor (NGF), a novel target for pain, began a dose ranging study in osteoarthritis of the knee. Trial results are expected during the first half of 2010. A Phase 1 study of REGN475 in healthy volunteers is also continuing, and Phase 1 studies are in progress with REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being studied in patients with advanced malignancies. We and sanofi-aventis expect to enter two more human monoclonal antibodies into clinical development this year and to advance an average of two to three into clinical development each year thereafter over the course of the next several years.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST® (rilonacept), as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

VelociSuite™

VelociSuite consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab™*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab™* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration with sanofi-aventis

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $75 million of research from the collaboration's inception through December 31, 2008 and will fund up to $100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made $20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, and 2009. AstraZeneca is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next additional payment. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made $20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next additional payment. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Academic *VelocImmune*® Investigators' Program

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. In March 2009, we entered into a similar agreement with The University of Texas Southwestern Medical Center at Dallas. Under the agreements, scientists at these academic institutions will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay to the appropriate institution a low single-digit royalty on ensuing product sales.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene*® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended, we are entitled to receive a minimum of $25.3 million over the five-year period beginning September 2006, including $1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and angiopoietins seems to be of value in either promoting or blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature,* we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. A fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune®* technology is being studied in a Phase 1 clinical trial in patients with advanced malignancies.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating lead monoclonal antibodies in relevant preclinical models.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting *in vivo* and *in vitro* experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2009, we had a cumulative loss of $904.6 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2009 and plans over the next 12 months are as follows:

Clinical Program	2009 Events to Date	2009-10 Plans (next 12 months)
ARCALYST® (rilonacept; also known as IL-1 Trap)	• Initiated patient enrollment in the Phase 3 program evaluating ARCALYST in the prevention of gout flares associated with the initiation of urate-lowering drug therapy and in the treatment of acute gout attacks	• Continue enrollment in the Phase 3 program in gout • Report initial data from Phase 3 gout program during the first half of 2010
Aflibercept (VEGF Trap – Oncology)	• Initiated a Phase 2 1st line study in metastatic colorectal cancer in combination with chemotherapy • Achieved more than 80% enrollment in each of the Phase 3 studies • Reported results of a Phase 2 single-agent study in symptomatic malignant ascites (SMA) • Discontinued a Phase 3 study in metastatic pancreatic cancer in combination with chemotherapy	• Continue enrollment of the Phase 3 studies in colorectal cancer, non-small cell lung cancer, and prostate cancer • During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study in colorectal cancer
VEGF Trap-Eye (intravitreal injection)	• Completed enrollment of patients in the Phase 3 wet AMD program (VIEW 1 and VIEW 2) • Completed enrollment of patients in the Phase 2 DME trial • Initiated a Phase 3 CRVO program	• Continue enrollment in Phase 3 CRVO trials • Report data from Phase 2 DME trial during the first half of 2010 • Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010
Monoclonal Antibodies	• Initiated a Phase 1 trial for REGN475 (anti-NGF) in healthy volunteers • Initiated a Phase 1 trial for REGN421(anti-Dll4) in oncology • Initiated a dose ranging study for REGN475 in osteoarthritis of the knee	• Report data from a Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis • Initiate a dose-ranging study for REGN88 in rheumatoid arthritis • Initiate additional Phase 2 trials for REGN475 in pain indications • Report data from the study of REGN475 in osteoarthritis of the knee during the first half of 2010 • Advance additional antibody candidate(s) into clinical development

Results of Operations

Three Months Ended September 30, 2009 and 2008

Net Loss:

Regeneron reported a net loss of $1.0 million, or $0.01 per share (basic and diluted), for the third quarter of 2009 compared to a net loss of $19.1 million, or $0.24 per share (basic and diluted), for the third quarter of 2008. The decrease in our net loss was principally due to higher contract research and development revenue in connection with our antibody collaboration with sanofi-aventis, and receipt of a $20.0 million research progress payment from Bayer HealthCare, partially offset by higher research and development expenses, as detailed below.

Revenues:

Revenues for the three months ended September 30, 2009 and 2008 consist of the following:

(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis	$ 68.5	$42.0
Bayer HealthCare	12.2	9.0
Other	1.8	1.9
Total contract research & development revenue	82.5	52.9
Research progress payment	20.0	
Technology licensing revenue	10.0	10.0
Net product sales	5.0	2.7
Total revenue	$117.5	$65.6

The contract research and development revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Contract Research & Development Revenue	Three months ended September 30,	
(In millions)	2009	2008
Aflibercept:		
Regeneron expense reimbursement	$ 7.0	$ 7.3
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total aflibercept	9.5	9.4
Antibody:		
Regeneron expense reimbursement	55.7	29.5
Recognition of deferred revenue related to up-front payment	2.6	2.6
Recognition of revenue related to *VelociGene*®agreement	0.7	0.5
Total antibody	59.0	32.6
Total sanofi-aventis contract research & development revenue	$ 68.5	$ 42.0

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the third quarter of 2009, compared to the same period in 2008, primarily due to lower costs related to internal research activities, partially offset by higher costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in the third quarter of 2009 compared to the same period in 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of September 30, 2009, $45.0 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In the third quarter of 2009, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $25.7 million under the discovery agreement and $30.0 million of development costs under the license agreement, compared to $24.1 million and $5.4 million, respectively, in the third quarter of 2008. The higher reimbursement amounts in the third quarter of 2009 compared to the same period in 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the license agreement.

Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' $85.0 million up-front payment. As of September 30, 2009, $65.7 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the three months ended September 30, 2009, we recognized $0.7 million of revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of deferred revenue related to a non-refundable $75.0 million up-front payment and $20.0 million non-substantive milestone payment.

Bayer HealthCare Contract Research & Development Revenue	Three months ended September 30,	
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 9.7	$ 5.7
Recognition of deferred revenue related to up-front and non-substantive milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	$ 12.2	$ 9.0

In the third quarter of 2009, cost-sharing of Regeneron VEGF Trap-Eye development expenses increased, compared to the same period in 2008, primarily due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. Recognition of deferred revenue related to Bayer's up-front and milestone payments decreased in the third quarter of 2009 compared to the same period in 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of September 30, 2009, $59.3 million of the up-front licensing and non-substantive milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue in the third quarter of 2009 and 2008 includes $1.4 million and $1.2 million, respectively, in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In July 2009, we received a $20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in revenues as a research progress payment for the three months ended September 30, 2009.

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the third quarter of both 2009 and 2008, we recognized $10.0 million of technology licensing revenue related to these agreements.

For the three months ended September 30, 2009, we recognized as revenue $5.0 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated, compared to $2.7 million for the same period in 2008. At September 30, 2009, deferred revenue related to ARCALYST net product sales totaled $5.0 million.

Expenses:

Total operating expenses increased to $118.7 million in the third quarter of 2009 from $83.5 million in the same period of 2008. Our average headcount increased to 998 in the third quarter of 2009 from 851 in the same period of 2008, principally as a result of our expanding research and development activities that are primarily attributable to the sanofi-aventis antibody collaboration.

Operating expenses in the third quarter of 2009 and 2008 include a total of $7.5 million and $8.2 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended September 30, 2009		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 100.8	$ 4.6	$ 105.4
Selling, general, and administrative	9.9	2.9	12.8
Cost of goods sold	0.5		0.5
Total operating expenses	$ 111.2	$ 7.5	$ 118.7

	For the three months ended September 30, 2008		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 67.1	$ 5.0	$ 72.1
Selling, general, and administrative	7.9	3.2	11.1
Cost of goods sold	0.3		0.3
Total operating expenses	$ 75.3	$ 8.2	$ 83.5

Research and Development Expenses:

Research and development expenses increased to $105.4 million in the third quarter of 2009 from $72.1 million in the same period of 2008. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2009 and 2008:

Research and Development Expenses	For the three months ended September 30,		
(In millions)	2009	2008	Increase
Payroll and benefits (1)	$ 24.5	$ 22.5	$ 2.0
Clinical trial expenses	29.4	14.7	14.7
Clinical manufacturing costs (2)	18.0	13.8	4.2
Research and preclinical development costs	11.1	8.7	2.4
Occupancy and other operating costs	10.5	8.8	1.7
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	11.9	3.6	8.3
Total research and development	$ 105.4	$ 72.1	$ 33.3

(1) Includes $3.9 million and $4.3 million of Non-cash Compensation Expense for the three months ended September 30, 2009 and 2008, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million of Non-cash Compensation Expense for both the three months ended September 30, 2009 and 2008.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent interim quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and recently initiated Phase 3 trial in CRVO, (ii) ARCALYST, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibodies, primarily related to REGN475 for the treatment of pain. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount and expanded research and development activities. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which is being conducted by Bayer HealthCare.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the three months ended September 30,		**Increase**
(In millions)	2009	2008	(Decrease)
ARCALYST® (rilonacept)	$ 15.5	$ 9.7	$ 5.8
Aflibercept	6.1	6.6	(0.5)
VEGF Trap-Eye	29.9	18.7	11.2
REGN88	10.0	5.4	4.6
REGN421 and REGN475	9.5		9.5
Other research programs & unallocated costs	34.4	31.7	2.7
Total research and development expenses	$ 105.4	$ 72.1	$ 33.3

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We project to ship approximately $20 million of ARCALYST to our U.S. distributors in 2009.

Selling, General, and Administrative Expenses:

Selling, general, and administrative expenses increased to $12.8 million in the third quarter of 2009 from $11.1 million in the same period of 2008 due primarily to (i) higher compensation and facility-related expenses due primarily to increases in administrative headcount to support our expanded research and development activities, (ii) higher patent-related costs, (iii) higher professional fees related to various corporate matters, and (iv) higher patient assistance costs related to ARCALYST,. These increases were partially offset by lower market research costs related to various programs and a decrease in recruitment costs for administrative headcount.

Cost of Goods Sold:

In the third quarter of 2008, we began recognizing revenue and cost of goods sold from product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for the third quarter of 2009 was $0.5 million, compared to $0.3 million for the same period of 2008, and consisted primarily of royalty and other period costs related to ARCALYST commercial supplies.

Other Income and Expense:

Investment income decreased to $0.9 million in the third quarter of 2009 from $3.7 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter of 2008. Interest expense decreased to $0.6 million in the third quarter of 2009 from $1.8 million in the comparable quarter of 2008. Interest expense in 2009 was attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. Interest expense in the third quarter of 2008 related to $200.0 million of formerly outstanding 5.5% Convertible Senior Subordinated Notes which we either repurchased or repaid in full during 2008. During the second and third quarters of 2008, we repurchased a total of $82.5 million in principal amount of these convertible notes for $83.3 million. In connection with the repurchases, we recognized a $7 thousand loss on early extinguishment of debt in the third quarter of 2008.

Income Tax Expense:

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years. As a result, we incurred income tax expense of $3.1 million, which relates to U.S. Federal and New York State alternative minimum tax and includes $0.2 million of interest and penalties.

Nine Months Ended September 30, 2009 and 2008

Net Loss:

Regeneron reported a net loss of $31.3 million, or $0.39 per share (basic and diluted), for the first nine months of 2009 compared to a net loss of $49.6 million, or $0.63 per share (basic and diluted), for the same period of 2008. The decrease in our net loss was principally due to higher contract research and development revenue in connection with our antibody collaboration with sanofi-aventis, receipt of a $20.0 million research progress payment from Bayer HealthCare, and higher ARCALYST® (rilonacept) sales, partially offset by higher research and development expenses, as detailed below.

Revenues:

Revenues for the nine months ended September 30, 2009 and 2008 consist of the following:

(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis	$178.9	$116.3
Bayer HealthCare	34.9	28.2
Other	5.3	5.4
Total contract research & development revenue	219.1	149.9
Research progress payment	20.0	
Technology licensing revenue	30.0	30.0
Net product sales	13.4	2.7
Total revenue	$282.5	$182.6

The contract and research development revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Contract Research & Development Revenue	Nine months ended September 30,	
(In millions)	2009	2008
Aflibercept		
Regeneron expense reimbursement	$ 21.6	$ 29.3
Recognition of deferred revenue related to up-front payments	7.4	6.2
Total aflibercept	29.0	35.5
Antibody		
Regeneron expense reimbursement	139.8	72.4
Recognition of deferred revenue related to up-front payment	7.9	7.9
Recognition of revenue related to *VelociGene®* agreement	2.2	0.5
Total antibody	149.9	80.8
Total sanofi-aventis contract research & development revenue	$ 178.9	$ 116.3

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first nine months of 2009, compared to the same period in 2008, primarily due to lower costs related to internal research activities and manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in the first nine months of 2009 compared to the same period in 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008.

In the first nine months of 2009, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $76.7 million under the discovery agreement and $63.1 million of development costs under the license agreement, compared to $56.5 million and $15.9 million, respectively, in the first nine months of 2008. The higher reimbursement amounts in the first nine months of 2009 compared to the same period in 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the license agreement.

As described above, in August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the nine months ended September 30, 2009, we recognized $2.2 million of revenue related to this agreement, compared to $0.5 million for the same period in 2008.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of deferred revenue related to a non-refundable $75.0 million up-front payment and $20.0 million non-substantive milestone payment.

Bayer HealthCare Contract Research & Development Revenue	Nine months ended September 30,	
(In millions)	2009	2008
Cost sharing of Regeneron VEGF Trap-Eye development expenses	$ 27.5	$ 18.3
Recognition of deferred revenue related to up-front and non-substantive milestone payments	7.4	9.9
Total Bayer HealthCare contract research & development revenue	$ 34.9	$ 28.2

In the first nine months of 2009, cost-sharing of Regeneron VEGF Trap-Eye development expenses increased, compared to the same period in 2008, primarily due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. Recognition of deferred revenue related to Bayer's up-front and non-substantive milestone payments decreased in the first nine months of 2009 compared to the same period in 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008.

Other contract research and development revenue in the first nine months of 2009 and 2008 includes $4.4 million and $3.6 million, respectively, in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In July 2009, we received a $20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in revenues as a research progress payment for the nine months ended September 30, 2009.

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first nine months of both 2009 and 2008, we recognized $30.0 million of technology licensing revenue related to these agreements.

For the nine months ended September 30, 2009, we recognized as revenue $13.4 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated, compared to $2.7 million for the same period in 2008.

Expenses:

Total operating expenses increased to $317.2 million in the first nine months of 2009 from $236.3 million in the same period of 2008. Our average headcount increased to 967 in the first nine months of 2009 from 778 in the same period of 2008 principally as a result of our expanding research and development activities that are primarily attributable to the sanofi-aventis antibody collaboration.

Operating expenses for the first nine months of 2009 and 2008 include a total of $22.6 million and $24.7 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the nine months ended September 30, 2009		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 266.0	$ 14.0	$ 280.0
Selling, general, and administrative	27.3	8.6	35.9
Cost of goods sold	1.3		1.3
Total operating expenses	$ 294.6	$ 22.6	$ 317.2

	For the nine months ended September 30, 2008		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 185.5	$ 14.8	$ 200.3
Selling, general, and administrative	25.8	9.9	35.7
Cost of goods sold	0.3		0.3
Total operating expenses	$ 211.6	$ 24.7	$ 236.3

Research and Development Expenses:

Research and development expenses increased to $280.0 million in the first nine months of 2009 from $200.3 million in the same period of 2008. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2009 and 2008:

Research and Development Expenses	For the nine months ended September 30,		
(In millions)	2009	2008	Increase
Payroll and benefits (1)	$ 71.0	$ 61.4	$ 9.6
Clinical trial expenses	78.9	35.2	43.7
Clinical manufacturing costs (2)	46.0	40.3	5.7
Research and preclinical development costs	29.5	21.6	7.9
Occupancy and other operating costs	27.9	22.8	5.1
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	26.7	19.0	7.7
Total research and development	$ 280.0	$ 200.3	$ 79.7

(1) Includes $11.8 million and $12.6 million of Non-cash Compensation Expense for the nine months ended September 30, 2009 and 2008, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $2.2 million of Non-cash Compensation Expense for both the nine months ended September 30, 2009 and 2008.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent interim quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO, (ii) ARCALYST, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibodies, primarily related to REGN88 in rheumatoid arthritis and REGN475 for the treatment of pain. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of ARCALYST and monoclonal antibodies, partially offset by lower costs related to manufacturing aflibercept clinical supplies. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount and expanded research and development activities. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which is being conducted by Bayer HealthCare.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs (including ARCALYST for the treatment of CAPS prior to receipt of marketing approval from the FDA in February 2008) are shown below:

Project Costs	For the nine months ended September 30,		Increase
(In millions)	2009	2008	(Decrease)
ARCALYST® (rilonacept)	$ 49.1	$ 24.9	$ 24.2
Aflibercept	17.7	25.4	(7.7)
VEGF Trap-Eye	77.7	57.6	20.1
REGN88	27.5	14.7	12.8
REGN421 and REGN475	19.4		19.4
Other research programs & unallocated costs	88.6	77.7	10.9
Total research and development expenses	$ 280.0	$ 200.3	$ 79.7

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2009 and 2008, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We project to ship approximately $20 million of ARCALYST to our U.S. distributors in 2009.

Selling, General, and Administrative Expenses:

Selling, general, and administrative expenses increased slightly to $35.9 million from $35.7 million for the first nine months of 2009 compared to 2008. In 2009, we incurred (i) higher compensation expense and facility-related expenses, due primarily to increases in administrative headcount to support our expanded research and development activities, (ii) higher selling expenses and patient assistance costs related to ARCALYST, and (iii) higher patent-related costs. These increases were offset by (i) lower market research costs related to various programs, (ii) a decrease in recruitment costs for administrative headcount, and (iii) lower professional fees related to various corporate matters.

Cost of Goods Sold:

In the third quarter of 2008, we began recognizing revenue and cost of goods sold from product sales of ARCALYST® (rilonacept). We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for the first nine months of 2009 was $1.3 million, compared to $0.3 million for the same period in 2008, and consisted primarily of royalty and other period costs related to ARCALYST commercial supplies.

Other Income and Expense:

Investment income decreased to $3.9 million in the first nine months of 2009 from $15.5 million in the comparable period of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first nine months of 2009 compared to the same period in 2008. Interest expense decreased to $0.6 million in the first nine months of 2009 from $7.5 million in the comparable period of 2008. Interest expense in 2009 was attributable to the imputed interest portion of the payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown. Interest expense in the first nine months of 2008 related to $200.0 million of formerly outstanding 5.5% Convertible Senior Subordinated Notes which we either repurchased or repaid in full during 2008. In the first nine months of 2008, we repurchased a total of $82.5 million in principal amount of these convertible notes for $83.3 million. In connection with the repurchases, we recognized a $0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs.

Income Tax Expense:

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years. As a result, we incurred income tax expense of $3.1 million, which relates to U.S. Federal and New York State alternative minimum tax and includes $0.2 million of interest and penalties.

Revision of Previously Issued Financial Statements

The application of authoritative guidance issued by the Financial Accounting Standards Board (FASB), under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

We revised our previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which we are leasing and to adjust our previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. We also revised our statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of our lease, with a corresponding adjustment to other long-term liabilities. In addition, we revised our statement of cash flows for the quarter ended March 31, 2009 to reclassify, from an operating activity to a financing activity, a $5.2 million reimbursement received from our landlord for tenant improvement costs we incurred. Under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation.

As previously disclosed, the above described revisions consisted entirely of non-cash adjustments. They had no impact on our business operations, existing capital resources, or our ability to fund our operating needs, including the preclinical and clinical development of our product candidates. The revisions also had no impact on our previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009 (as described above), had no impact on our previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on our previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, we determined that the judgment of a reasonable person relying on our previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to our balance sheets as of the dates set forth below is as follows:

Balance Sheet Impact at December 31, 2007 and 2008, and March 31, 2009
(in millions)

	December 31, 2007	December 31, 2008	March 31, 2009
As originally reported			
Property, plant, and equipment, net	$ 58.3	$ 87.9	$ 109.8
Total assets	936.3	670.0	681.4
Other long-term liabilities		5.1	13.2
Total liabilities	476.0	251.2	271.1
Accumulated deficit	(793.2)	(875.9)	(893.4)
Total stockholders' equity	460.3	418.8	410.3
Total liabilities and stockholders' equity	936.3	670.0	681.4
As revised			
Property, plant, and equipment, net	$ 79.9	$ 142.0	$ 164.6
Total assets	957.9	724.2	736.2
Facility lease obligation	21.6	54.2	60.0
Other long-term liabilities	0.9	2.4	3.2
Total liabilities	498.5	302.7	321.1
Accumulated deficit	(794.1)	(873.3)	(888.7)
Total stockholders' equity	459.4	421.5	415.1
Total liabilities and stockholders' equity	957.9	724.2	736.2

For comparative purposes, the impact of the above described revisions to our statements of operations and statement of cash flows for the period(s) set forth below is as follows:

Statements of Operations Impact for the three, six, and nine month periods ended March 31, June 30 and September 30, 2008, the years ended December 31, 2007 and 2008, and the three months ended March 31, 2009
(in millions, except per share data)

	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2007	December 31, 2008	March 31, 2009
As originally reported						
Research and development expenses	$ 61.3	$ 127.8	$ 201.7	$ 201.6	$278.0	$ 82.1
Selling, general, and administrative expenses	11.0	24.5	35.9	37.9	49.3	11.7
Total expenses	72.3	152.3	237.9	239.5	328.3	94.2
Net loss	(11.6)	(30.1)	(51.2)	(105.6)	(82.7)	(17.5)
Net loss per share, basic and diluted	$ (0.15)	$ (0.38)	$ (0.65)	$ (1.59)	$ (1.05)	$ (0.22)
As revised						
Research and development expenses	$ 61.5	$ 128.2	$ 200.3	$ 202.5	$274.9	$ 80.3
Selling, general, and administrative expenses	11.1	24.6	35.7	37.9	48.9	11.4
Total expenses	72.5	152.8	236.3	240.4	324.7	92.1
Net loss	(11.8)	(30.5)	(49.6)	(106.5)	(79.1)	(15.4)
Net loss per share, basic and diluted	$ (0.15)	$ (0.39)	$ (0.63)	$ (1.61)	$ (1.00)	$ (0.19)

Statement of Cash Flows Impact for the three months ended March 31, 2009
(in millions)

	As Originally Reported	As Revised
Net cash used in operating activities	$ (10.2)	$ (15.4)
Net cash used in investing activities	(39.5)	(39.5)
Net cash provided by financing activities	1.0	6.2
Net decrease in cash and cash equivalents	$ (48.7)	$ (48.7)

These revised amounts, as applicable, are reflected in this Quarterly Report on Form 10-Q for the period ended September 30, 2009, and will be included in our Annual Report on Form 10-K for the year ended December 31, 2009 and our Quarterly Report on Form 10-Q for the period ended March 31, 2010.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST® (rilonacept) product revenue, and investment income.

Nine months ended September 30, 2009 and 2008

At September 30, 2009, we had $438.6 million in cash, cash equivalents, restricted cash, and marketable securities compared with $527.5 million at December 31, 2008. In February 2009, we received a $20.0 million annual, non-refundable payment in connection with our non-exclusive license agreement with AstraZeneca. In May 2009, we received a $20.0 million annual, non-refundable payment in connection with our non-exclusive license agreement with Astellas. In July 2009, we received a $20.0 million milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO.

Cash Used in Operations:

Net cash used in operations was $25.8 million in the first nine months of 2009 compared to $53.2 million in the first nine months of 2008. Our net losses of $31.3 million in the first nine months of 2009 and $49.6 million in the first nine months of 2008 included $22.6 million and $24.7 million, respectively, of Non-cash Compensation Expense.

At September 30, 2009, accounts receivable increased by $32.6 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2009 decreased by $11.4 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the receipt of the $20.0 million payments from AstraZeneca and Astella, as described above, which were deferred and are being recognized ratably over the ensuing year. At September 30, 2009, accounts payable, accrued expenses, and other liabilities increased by $18.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a $7.0 million decrease in the cost-sharing payment due to Bayer HealthCare at September 30, 2009 compared to December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration.

At September 30, 2008, accounts receivable increased by $23.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2008 decreased by $10.1 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by (i) the receipt of $20.0 million payments from AstraZeneca in February 2008 and Astellas in June 2008, which were deferred and recognized ratably over the ensuing year, and (ii) deferral of $3.8 million of ARCALYST® (rilonacept) net product sales at September 30, 2008.

Cash Provided by (Used in) Investing Activities:

Net cash provided by investing activities was $19.3 million in the first nine months of 2009 compared to net cash used in investing activities of $53.9 million in the same period of 2008, due primarily to a decrease in purchases of marketable securities net of sales or maturities. In the first nine months of 2009, sales or maturities of marketable securities exceeded purchases by $94.3 million, whereas in the first nine months of 2008, purchases of marketable securities exceeded sales or maturities by $34.7 million. In addition, cash used for capital expenditures totaled $75.0 million in the first nine months of 2009, primarily for tenant improvements and related costs in connection with our new leased facilities in Tarrytown.

Cash Provided by (Used in) Financing Activities:

Net cash provided by financing activities was $9.0 million in the first nine months of 2009 compared to net cash used in financing activities of $77.1 million in the same period in 2008. In the first nine months of 2009, we received a $5.2 million reimbursement of tenant improvements from our landlord in connection with our new Tarrytown facilities, which we are deemed to own in accordance with FASB authoritative guidance. In the first nine months of 2008, we repurchased $82.5 million in principal amount of our convertible senior subordinated notes for $83.3 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $4.6 million and $6.2 million in the first nine months of 2009 and 2008, respectively.

Fair Value of Marketable Securities:

At September 30, 2009 and December 31, 2008, we held marketable securities whose aggregate fair value totaled $186.7 million and $278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	September 30, 2009		December 31, 2008	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$ 80.5	43%	$ 113.9	41%
U.S. government agency securities	24.9	13%	58.3	21%
U.S. government-guaranteed corporate bonds	49.1	26%	29.8	11%
U.S. government guaranteed collateralized mortgage obligations	4.8	3%	17.4	6%
Corporate bonds	16.1	9%	37.1	13%
Mortgage-backed securities	4.2	2%	10.0	4%
Other asset-backed securities			7.8	3%
Other	7.1	4%	3.7	1%
Total marketable securities	$ 186.7	100%	$ 278.0	100%

In addition, at September 30, 2009 and December 31, 2008, we had $251.9 million and $249.5 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During the first nine months of 2009, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations, and U.S. government-guaranteed debt. This shift toward higher quality securities, which we initiated in 2008, continues to reduce the risk profile, as well as the overall yield, of our portfolio. In particular, we continue to reduce the proportion of asset-backed securities and corporate bonds in our portfolio.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled $75.0 million and $19.1 million for the first nine months of 2009 and 2008, respectively. During the remainder of 2009, we expect to incur approximately $10 to $15 million in capital expenditures, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our new leased Tarrytown facilities, which will be funded by our existing capital resources. In October 2009, we received $16.9 million from our landlord as partial reimbursement of tenant improvement costs we incurred in Tarrytown. An additional $33 million is reimbursable at our option at any time through June 2010 under the terms of our Tarrytown lease.

Amendment to Lease – Tarrytown, New York Facilities:

We currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, including approximately 230,000 square feet in newly constructed facilities that were completed during the third quarter of 2009. The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, we amended the lease agreement to increase the amount of space we will lease to approximately 389,500 square feet. As amended, the lease contains early termination options on approximately 159,500 square feet of space. Other terms and conditions, as previously described in our Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, we terminated a sublease for 16,200 square feet of space in Tarrytown, New York.

Facility Lease Obligation:

As described above, in connection with the application of FASB authoritative guidance to our lease of office and laboratory facilities constructed in Tarrytown, New York by our landlord, we capitalized the landlord's costs of constructing the new facilities, which totaled $58.2 million as of September 30, 2009, and recognized a corresponding facility lease obligation of $58.2 million. We also recognized, as an additional facility lease obligation, a $5.2 million reimbursement received from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service in September 2009. For the three and nine months ended September 30, 2009, we recognized $0.6 million of interest expense in connection with the facility lease obligation in our statement of operations. At September 30, 2009, the facility lease obligation balance was $62.6 million.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 50-60% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST® (rilonacept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 20-30% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 sales of ARCALYST® (rilonacept) for the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with the April 2009 amendment to our lease agreement for facilities in Tarrytown, New York, as described above, our total estimated future minimum noncancelable lease commitments, previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008, will increase (i) from $9.1 million to $9.4 million for the year ending December 31, 2009, (ii) from $26.8 million to $29.2 million for the two-year period beginning January 1, 2010, (iii) from $27.2 million to $28.8 million for the two-year period beginning January 1, 2012, and (iv) from $167.0 million to $182.5 million for the eleven-year period beginning January 1, 2014.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs.

Other than a $1.6 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of September 30, 2009, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement by requiring the use of estimated selling price to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We are required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. We are currently evaluating the impact that this guidance will have on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate, asset-backed, and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a $0.9 million and $1.7 million decrease in the fair value of our investment portfolio at September 30, 2009 and 2008, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of $5.9 million, $2.5 million and $0.1 million in 2007, 2008, and the first nine months of 2009, respectively.

The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in our investment portfolio and that such declines could result in charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2009, we had a cumulative loss of $904.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of September 30, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled $438.6 million and represented 59% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and to a lesser extent, asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $186.7 million at September 30, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of $5.9 million, $2.5 million and $0.1 million in 2007, 2008, and the first nine months of 2009, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd line metastatic colorectal cancer, 1st line androgen independent prostate cancer, and 2nd line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In September 2009, we announced the discontinuation of a Phase 3 clinical trial that evaluated aflibercept plus gemcitabine versus placebo plus gemcitabine for the first-line treatment of metastatic pancreatic cancer after an Independent Data Monitoring Committee for the trial determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of Central Retinal Vein Occlusion (CRVO). Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis® (ranibizumab injection), marketed by Genentech, Inc. A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

ARCALYST is in Phase 3 clinical trials for two different gout indications – the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that ARCALYST will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of ARCALYST in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could harm the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® (rilonacept) in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® (rilonacept) for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST and the EMEA approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of rilonacept or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states and also at the federal level. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure, and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and current pending legislation which would ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs) or good clinical practices, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® (rilonacept) and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In June 2009, Novartis received marketing approval from the FDA for its IL-1 antibody product for the treatment of CAPS. In October 2009 we received European marketing authorization for rilonacept for CAPS and Novartis received European marketing authorization for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (bevacizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline plc. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® (ranibizumab injection), marketed by Genentech, Inc., for the treatment of age-related macular degeneration (wet AMD) and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab), with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis to Avastin in the treatment of wet AMD. The marketing approval of Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis, because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., Remicade® (infliximab), marketed by Centocor Ortho Biotech, Inc., Humira® (adalimumab), marketed by Abbott Laboratories, and Simponi™ (golimumab), marketed by Centocor Ortho Biotech, Inc., and the IL-1 receptor antagonist Kineret® (anakinra) marketed by Biovitrum, and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® (rilonacept). This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. As noted above, Novartis is testing its IL-1 antibody in gout. Novartis' product candidate is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST in the United States for the treatment of a group of rare genetic disorders called CAPS. We recently received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2009, our five largest shareholders beneficially owned 42.0% of our outstanding shares of Common Stock, assuming, in the case of our Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2009. As of September 30, 2009, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.9% of the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2009, holders of Class A Stock held 22.3% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of September 30, 2009:

- our current executive officers and directors beneficially owned 13.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2009, and 28.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2009; and
- our five largest shareholders beneficially owned 42.0% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2009. In addition, these five shareholders held 48.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2009.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: November 3, 2009

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2009

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2009

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
November 3, 2009

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
November 3, 2009

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 4/29/2010

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2010

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York (Address of principal executive offices)	10591-6707 (Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No_____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes_____ No_____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer __

Non-accelerated filer __ (Do not check if a smaller reporting company) Smaller reporting company__

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes_____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of April 14, 2010:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,182,036
Common Stock, $0.001 par value	79,730,517

REGENERON PHARMACEUTICALS, INC.
Table of Contents
March 31, 2010

		Page Numbers
PART I	FINANCIAL INFORMATION	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at March 31, 2010 and December 31, 2009	3
	Condensed statements of operations (unaudited) for the three months ended March 31, 2010 and 2009	4
	Condensed statements of stockholders' equity (unaudited) for the three months ended March 31, 2010 and 2009	5
	Condensed statements of cash flows (unaudited) for the three months ended March 31, 2010 and 2009	6
	Notes to condensed financial statements (unaudited)	7-14
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	15-33
Item 3	Quantitative and Qualitative Disclosures About Market Risk	33
Item 4	Controls and Procedures	33-34
PART II	OTHER INFORMATION	
Item 1	Legal Proceedings	34
Item 1A	Risk Factors	34-50
Item 6	Exhibits	50
SIGNATURE PAGE		51

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT MARCH 31, 2010 AND DECEMBER 31, 2009 (Unaudited)
(In thousands, except share data)

ASSETS	March 31, 2010	December 31, 2009
Current assets		
Cash and cash equivalents	$ 117,311	$ 207,075
Marketable securities	186,328	134,255
Accounts receivable from the sanofi-aventis Group	68,838	62,703
Accounts receivable - other	3,020	2,865
Prepaid expenses and other current assets	19,947	18,610
Total current assets	395,444	426,508
Restricted cash	1,600	1,600
Marketable securities	108,278	47,080
Property, plant and equipment, at cost, net of accumulated depreciation and amortization	274,621	259,676
Other assets	7,213	7,338
Total assets	$ 787,156	$ 741,202
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 53,905	$ 49,031
Deferred revenue from sanofi-aventis, current portion	17,784	17,523
Deferred revenue - other, current portion	31,969	27,021
Facility lease obligations, current portion	435	
Total current liabilities	104,093	93,575
Deferred revenue from sanofi-aventis	91,684	90,933
Deferred revenue - other	44,504	46,951
Facility lease obligations	156,464	109,022
Other long term liabilities	4,140	3,959
Total liabilities	400,885	344,440
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,211,698 in 2010 and 2,214,698 in 2009	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 79,690,055 in 2010 and 78,860,862 in 2009	80	79
Additional paid-in capital	1,357,089	1,338,732
Accumulated deficit	(971,617)	(941,095)
Accumulated other comprehensive income	717	1,044
Total stockholders' equity	386,271	396,762
Total liabilities and stockholders' equity	$ 787,156	$ 741,202

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended March 31,	
	2010	2009
		(Revised - see Note 8)
Revenues		
Sanofi-aventis collaboration revenue	$ 68,671	$ 49,660
Other collaboration revenue	13,087	9,948
Technology licensing	10,038	10,000
Net product sales	9,852	3,891
Contract research and other	1,886	1,482
	103,534	74,981
Expenses		
Research and development	117,471	80,307
Selling, general, and administrative	14,005	11,420
Cost of goods sold	717	392
	132,193	92,119
Loss from operations	(28,659)	(17,138)
Other income (expense)		
Investment income	439	1,750
Interest expense	(2,084)	
	(1,645)	1,750
Net loss before income tax expense	(30,304)	(15,388)
Income tax expense	218	
Net loss	$ (30,522)	$ (15,388)
Net loss per share, basic and diluted	$ (0.38)	$ (0.19)
Weighted average shares outstanding, basic and diluted	81,188	79,496

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2010 and 2009
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2009	2,245	$ 2	78,561	$ 79	$ 1,326,732	$ (941,065)	$ 1,044	$ 386,792	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			685	1	8,656			8,657	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867			2,867	
Conversion of Class A Stock to Common Stock	(33)		33						
Stock-based compensation expense					8,934			8,934	
Net loss						(30,522)		(30,522)	$ (30,522)
Change in net unrealized gain on marketable securities, net of tax benefit of $0.4 million							(427)	(427)	(427)
Balance, March 31, 2010	2,212	$ 2	79,390	$ 80	$ 1,347,089	$ (971,587)	$ 617	$ 376,201	$ (30,949)
Balance, December 31, 2008	2,249	$ 2	77,642	$ 78	$ 1,294,813	$ (973,265)	$ (134)	$ 321,514	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			117		1,038			1,038	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock-based compensation expense					7,654			7,654	
Net loss						(15,388)		(15,388)	$ (15,388)
Change in net unrealized loss on marketable securities							(1,134)	(1,134)	(1,134)
Balance, March 31, 2009 *(Revised - see Note 8)*	2,247	$ 2	77,842	$ 78	$ 1,304,896	$ (988,653)	$ (1,268)	$ 314,055	$ (16,522)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Three months ended March 31,	
	2010	2009
		(Revised - see Note 8)
Cash flows from operating activities		
Net loss	$ (30,522)	$ (15,388)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	4,183	2,724
Non-cash compensation expense	8,834	7,854
Other non-cash charges and expenses	470	
Changes in assets and liabilities		
Increase in accounts receivable	(6,290)	(12,997)
Increase in prepaid expenses and other assets	(2,483)	(8,611)
Increase in deferred revenue	3,513	3,194
Increase in accounts payable, accrued expenses and other liabilities	12,294	8,043
Total adjustments	20,521	7
Net cash used in operating activities	(10,001)	(15,381)
Cash flows from investing activities		
Purchases of marketable securities	(177,594)	(100,315)
Sales or maturities of marketable securities	64,359	82,694
Capital expenditures	(22,743)	(21,917)
Net cash used in investing activities	(135,978)	(39,538)
Cash flows from financing activities		
Proceeds in connection with facility lease obligations	47,544	5,182
Payments in connection with facility lease obligations	(555)	
Net proceeds from the issuance of Common Stock	9,226	1,038
Net cash provided by financing activities	56,215	6,220
Net decrease in cash and cash equivalents	(89,764)	(48,699)
Cash and cash equivalents at beginning of period	207,075	247,796
Cash and cash equivalents at end of period	$ 117,311	$ 199,097

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2009 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009. In addition, the previously issued condensed statements of operations, stockholders' equity, and cash flows for the three months ended March 31, 2009, contained in the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2009, have been revised in this Quarterly Report on Form 10-Q with respect to the Company's December 2006 lease of office and laboratory facilities in Tarrytown, New York by applying authoritative guidance issued by the Financial Accounting Standards Board (FASB). See Note 8 below.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, was extended. The effect of this change in estimate was to lower depreciation expense by $1.0 million and to lower the Company's net loss per share by $0.01 for the three months ended March 31, 2010.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® (rilonacept) beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® (rilonacept) net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST® (rilonacept). As a result, for the three months ended March 31, 2010, the Company recognized as revenue $9.9 million of ARCALYST® (rilonacept) net product sales, which included $5.1 million of ARCALYST® (rilonacept) net product sales made during the quarter and $4.8 million of previously deferred net product sales. For the three months ended March 31, 2009, the Company recognized as revenue $3.9 million of ARCALYST® (rilonacept) net product sales. There was no deferred ARCALYST® (rilonacept) net product sales revenue at March 31, 2010. At March 31, 2009, deferred ARCALYST® (rilonacept) net product sales revenue was $4.2 million. The effect of this change in estimate related to ARCALYST® (rilonacept) net product sales revenue was to lower the Company's net loss per share by $0.06 for the three months ended March 31, 2010.

Cost of goods sold related to ARCALYST® (rilonacept) sales, which consisted primarily of royalties, totaled $0.7 million and $0.4 million for the three months ended March 31, 2010 and 2009, respectively. To date, ARCALYST® (rilonacept) shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® (rilonacept); therefore, the costs of these supplies were not included in costs of goods sold. At both March 31, 2010 and December 31, 2009, the Company had $0.4 million of inventoried work-in-process costs related to ARCALYST® (rilonacept), which is included in prepaid expenses and other current assets.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three months ended March 31, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March 31,	
	2010	2009
Net loss (Numerator)	$ (30,522)	$ (15,388)
Weighted average shares, in thousands (Denominator)	81,169	79,198
Basic and diluted net loss per share	$ (0.38)	$ (0.19)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the March 31, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended March 31,	
	2010	2009
Stock Options:		
Weighted average number, in thousands	21,400	20,216
Weighted average exercise price	$ 18.59	$ 17.55
Restricted Stock:		
Weighted average number, in thousands	501	500

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2010 and December 31, 2009 were $5.4 million and $9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2009 and December 31, 2008 were $9.8 million and $7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were $2.6 million and $1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 8), the Company recognized a facility lease obligation of $0.6 million for the three months ended March 31, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at March 31, 2010 was $0.8 million of capitalized and deferred interest for the quarter ended March 31, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at March 31, 2010 and December 31, 2009 were $0.1 million and $0.7 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at March 31, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2009 and December 31, 2008 were $2.5 million and $1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at March 31, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $4.8 million and $5.5 million at March 31, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was $4.0 million at both March 31, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at March 31, 2010 and December 31, 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair	Unrealized		
At March 31, 2010	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	$ 149,697	$149,688	$ 33	$ (42)	$ (9)
U.S. government guaranteed corporate bonds	23,822	23,956	136	(2)	134
Corporate bonds	8,152	8,248	96		96
Mortgage-backed securities	1,255	1,134		(121)	(121)
U.S. government guaranteed collateralized mortgage obligations	3,170	3,302	132		132
	186,096	186,328	397	(165)	232
Maturities between one and three years					
U.S. government obligations	59,524	59,487	13	(50)	(37)
U.S. government guaranteed corporate bonds	40,001	40,376	390	(15)	375
Mortgage-backed securities	1,517	1,439		(78)	(78)
Municipal bonds	2,217	2,208		(9)	(9)
	103,259	103,510	403	(152)	251
	$ 289,355	$289,838	$ 800	$ (317)	$ 483
At December 31, 2009					
Maturities within one year					
U.S. government obligations	$ 100,491	$100,573	$ 82		$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
Mortgage-backed securities	2,471	2,338		$ (133)	(133)
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
	133,892	134,255	496	(133)	363

At December 31, 2009 (continued)	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,645	41,611	280	(314)	(34)
	$ 135,537	$175,866	$ 770	$ (447)	$ 323

At March 31, 2010 and December 31, 2009, marketable securities included an additional unrealized gain of $0.7 million and $1.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at March 31, 2010 and December 31, 2009. The debt securities listed at March 31, 2010 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
At March 31, 2010	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government obligations	$ 121,293	$ (92)			$ 121,293	$ (92)
U.S. government guaranteed corporate bond	12,362	(17)			12,362	(17)
Mortgage-backed securities			2,572	(199)	2,572	(199)
Municipal bonds	2,209	(9)			2,209	(9)
	$ 135,864	$ (118)	$ 2,572	$ (199)	$ 138,436	$ (317)
At December 31, 2009						
U.S. government obligations	$ 9,367	$ (46)			$ 9,367	$ (46)
Mortgage-backed securities			$ 3,238	$ (401)	3,238	(401)
	$ 9,367	$ (46)	$ 3,238	$ (401)	$ 12,605	$ (447)

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2010 and 2009, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at March 31, 2010 and December 31, 2009, were as follows:

		Fair Value Measurements at Reporting Date Using		
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At March 31, 2010				
Available-for-sale marketable securities				
U.S. government obligations	$ 209,175		$ 209,175	
U.S. government guaranteed corporate bonds	64,332		64,332	
Corporate bonds	8,248		8,248	
Mortgage-backed securities	2,573		2,573	
U.S. government guaranteed collateralized mortgage obligations	3,302		3,302	
Municipal bonds	2,208		2,208	
Equity securities	4,768	$ 4,768		
	$ 294,606	$ 4,768	$ 289,838	
At December 31, 2009				
Available-for-sale marketable securities				
U.S. government obligations	$ 109,940		$ 109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
Mortgage-backed securities	3,238		3,238	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Equity securities	5,469	$ 5,469		
	$ 181,335	$ 5,469	$ 175,866	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the three months ended March 31, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the securities $1.1 million carrying value. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended March 31, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At March 31, 2009 and December 31, 2008, the Company held one Level 3 marketable security whose fair value was $0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the three months ended March 31, 2009, the Company did not record any settlements, realized gains or losses, or charges for other-than-temporary impairment related to this Level 3 marketable security. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three months ended March 31, 2009. The Company held no Level 3 marketable securities at March 31, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2010 and 2009.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment and the deterioration in the credit quality of issuers of securities that the Company holds increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2010 and December 31, 2009 consist of the following:

	March 31, 2010	December 31, 2009
Accounts payable	$ 14,315	$ 18,638
Accrued payroll and related costs	11,026	9,444
Accrued clinical trial expense	14,880	11,673
Accrued property, plant, and equipment expenditures	4,181	1,883
Accrued expenses, other	7,629	6,207
Payable to Bayer HealthCare	1,874	1,186
	$ 53,905	$ 49,031

7. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three months ended March 31, 2010 and 2009, the components of comprehensive loss are:

	Three months ended March 31,	
	2010	2009
Net loss	$ (30,522)	$ (15,388)
Change in net unrealized gain (loss) on marketable securities	(545)	(1,134)
Tax benefit of decrease in net unrealized gain on marketable securities	218	
Total comprehensive loss	$ (30,849)	$ (16,522)

8. Revisions of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, the Company became aware that certain of these conditions were applicable to its December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

As previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2009, the Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability). The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities. In addition, the Company's statement of cash flows for the quarter ended March 31, 2009 was revised to reclassify, from an operating activity to a financing activity, a $5.2 million reimbursement received from the Company's landlord for tenant improvement costs that the Company incurred. Under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation.

The above described revisions consisted entirely of non-cash adjustments. They had no impact on the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs. The revisions also had no impact on the Company's previously reported net increases or decreases in cash and cash equivalents. In addition, these revisions had no impact on the Company's previously reported current assets, current liabilities, and operating revenues. The Company did not amend previously issued financial statements because, after considering both qualitative and quantitative factors, the Company determined that the judgment of a reasonable person relying on the Company's previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to the Company's statement of operations, statement of stockholders' equity, and statement of cash flows for the three months ended March 31, 2009 is as follows:

Statement of Operations Impact for the three months ended March 31, 2009
(In millions, except per share data)

	As Originally Reported	As Revised
Research and development expenses	$ 82.1	$ 80.3
Selling, general, and administrative expenses	11.7	11.4
Total expenses	94.2	92.1
Net loss	(17.5)	(15.4)
Net loss per share, basic and diluted	$ (0.22)	$ (0.19)

Statement of Stockholders' Equity Impact for the three months ended March 31, 2009
(In millions)

	As Originally Reported	As Revised
Accumulated deficit	$ (695.4)	$ (557.7)
Total stockholders' equity	$ 410.3	$ 415.1

Statement of Cash Flows Impact for the three months ended March 31, 2009
(In millions)

	As Originally Reported	As Revised
Net cash used in operating activities	$ (10.2)	$ (15.4)
Net cash used in investing activities	(39.5)	(39.5)
Net cash provided by financing activities	1.0	6.2
Net decrease in cash and cash equivalents	$ (48.7)	$ (48.7)

These revised amounts are reflected in the Company's financial statements included in this Quarterly Report on Form 10-Q for the period ended March 31, 2010.

9. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

10. Future Impact of Recently Issued Accounting Standards

In March 2009, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will be required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite™* technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene®* technology to understand the role of these proteins in normal physiology as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune®*) and cell line expression technologies (*VelociMab®*) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials were developed using *VelocImmune®*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) – Cryopyrin-Associated Periodic Syndromes (CAPS)

We recognized $9.9 million of net product sales of ARCALYST® (rilonacept) Injection for Subcutaneous Use in the first quarter of 2010, which included $5.1 million of ARCALYST® (rilonacept) net product sales made during the quarter and $4.8 million of previously deferred net product sales, as described below under "Results of Operations." In the same quarter of 2009, we recognized $3.9 million of ARCALYST® (rilonacept) net product sales. ARCALYST® (rilonacept) is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

ARCALYST® (rilonacept) is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency for the treatment of CAPS with severe symptoms in adults and children 12 and older. Rilonacept is not currently marketed in the European Union. We own worldwide rights to ARCALYST® (rilonacept).

Clinical Programs:

1. Rilonacept – Inflammatory Diseases

We are evaluating rilonacept in gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation. Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with rilonacept for the treatment of gout. The program includes four clinical trials. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy. SURGE and PRE-SURGE 1 are fully enrolled. We expect to report initial data from SURGE and PRE-SURGE 1 during the second quarter of 2010 and from PRE-SURGE 2 and RE-SURGE during the first half of 2011. We own worldwide rights to rilonacept.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for gout, type 2 diabetes, and other inflammatory diseases.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare are also conducting a Phase 3 program in central retinal vein occlusion (CRVO).

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in late 2010.

The Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye dosing regimens versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ($p < 0.01$ for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. The COPERNICUS study was initiated during the third quarter of 2009 and is fully enrolled. The GALILEO study was initiated in October 2009 and is approximately half enrolled. Initial data are anticipated in early 2011.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to $70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with FOLFOX (folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a prespecified number of events have occurred in each trial. Based on projected event rates, (i) an interim analysis of VELOUR is expected to be conducted by an independent statistician and reviewed by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be reviewed by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF generated using our *VelocImmune*® technology. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4/5, or BDNF.

In the third quarter of 2009, we began a Phase 2 double-blind, placebo-controlled, dose-ranging, proof-of-concept study of REGN475 in persons with osteoarthritis of the knee. Preliminary data from that study are expected in the second quarter of 2010. Additionally, four Phase 2 proof-of-concept studies in other pain indications were initiated in late 2009 and early 2010. One of these studies, in patients with thermal injuries, is being discontinued because of difficulty enrolling patients. REGN475 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune*® technology that is in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune*® technology. REGN421 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

7. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR, which prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune*® technology to derive a fully human monoclonal antibody called REGN727 that is designed to bind to PCSK9 and prevent it from inhibiting LDLR. REGN727 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

8. REGN668 (Anti-IL-4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL-4R) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune*® antibody that is designed to bind to IL-4R. REGN668 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST® (rilonacept), as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®*, *VelociGene®*, *VelociMouse®*, and *VelociMab®*. The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune®* and our entire *VelociSuite™* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune®* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene*® platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made $20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of $20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune*® technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made $20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the second quarter of 2010. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune*® technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received $17.0 million through March 31, 2010 and are entitled to receive an additional $8.3 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® (rilonacept) or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the U.S. Food and Drug Administration (FDA) and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2010, we had a cumulative loss of $971.6 million. In the absence of significant revenues from the commercialization of ARCALYST® (rilonacept) or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and rilonacept; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2010 and plans over the next 12 months are as follows:

Clinical Program	2010 Events to Date	2010-11 Plans (next 12 months)
Rilonacept (also known as IL-1 Trap)	• Completed patient enrollment in the first of two Phase 3 trials (PRE-SURGE 1) evaluating rilonacept in the prevention of gout flares associated with the initiation of urate-lowering drug therapy • Completed patient enrollment in a Phase 3 study (SURGE) evaluating rilonacept in the treatment of acute gout flares	• Report data from SURGE and PRE-SURGE 1 during the second quarter of 2010 • Complete patient enrollment of the remaining Phase 3 studies in gout
VEGF Trap-Eye (intravitreal injection)	• Reported positive 24-week primary endpoint results from the Phase 2 DME trial • Completed patient enrollment in the first of two Phase 3 CRVO trials (COPERNICUS)	• Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 • Complete patient enrollment in the second Phase 3 CRVO trial (GALILEO) and report initial data from both trials • Report one-year results from the Phase 2 DME trial
Aflibercept (VEGF Trap – Oncology)	• Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer, prostate cancer, and colorectal cancer • Completed patient enrollment in a Phase 2 1st line study in metastatic colorectal cancer in combination with chemotherapy	• During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study in colorectal cancer
Monoclonal Antibodies	• REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis	• REGN475: Report data from the study in osteoarthritis of the knee during the second quarter of 2010 and from another study in a pain indication during the second half of 2010 • REGN727: Report proof-of-concept data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction • REGN668: Initiate a Phase 2 program in the treatment of a chronic allergic condition • REGN88: Report data from a Phase 1 trial in rheumatoid arthritis • Advance additional antibody candidates into clinical development

Results of Operations

Three Months Ended March 31, 2010 and 2009

Net Loss

Regeneron reported a net loss of $30.5 million, or $0.38 per share (basic and diluted), for the first quarter of 2010, compared to a net loss of $15.4 million, or $0.19 per share (basic and diluted) for the first quarter of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher contract research and development revenue primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended March 31, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue:		
Sanofi-aventis	$ 68.7	$49.6
Bayer HealthCare	13.1	10.0
Total collaboration revenue	81.8	59.6
Technology licensing revenue	10.0	10.0
Net product sales	9.9	3.9
Contract research and other revenue	1.8	1.5
Total revenue	$103.5	$75.0

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue

(In millions)	Three months ended March 31,	
	2010	2009
Aflibercept:		
Regeneron expense reimbursement	$ 4.9	$ 5.4
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total aflibercept	7.4	7.9
Antibody:		
Regeneron expense reimbursement	59.3	38.4
Recognition of deferred revenue related to up-front and other payments	1.6	2.6
Recognition of revenue related to *VelociGene®* agreement	0.4	0.7
Total antibody	61.3	41.7
Total sanofi-aventis collaboration revenue	$ 68.7	$ 49.6

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first quarter of 2010 compared to same period in 2009, primarily due to lower costs related to internal research activities. As of March 31, 2010, $40.0 million of the original $105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In the first quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of $26.7 million under the discovery agreement and $32.6 million of development costs under the license agreement, compared to $22.7 million and $15.7 million, respectively, in the first quarter of 2009. The higher reimbursement amounts in the first quarter of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenues related primarily to sanofi-aventis' $85.0 million up-front payments decreased during the first quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $5.1 million was received or receivable from sanofi-aventis as of March 31, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment. As of March 31, 2010, $67.2 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the three months ended March 31, 2010 and 2009, we recognized $0.4 million and $0.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue *(In millions)*	Three months ended March 31,	
	2010	2009
Cost sharing of Regeneron VEGF Trap-Eye development expenses	$ 10.6	$ 7.5
Recognition of deferred revenue related to up-front and milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 13.1	$ 10.0

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first quarter of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of March 31, 2010, $54.4 million of the $75.0 million up-front licensing and $20.0 million milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first quarter of both 2010 and 2009, we recognized $10.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS. We had limited historical return experience for ARCALYST® (rilonacept) beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® (rilonacept) net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST® (rilonacept). As a result, for the three months ended March 31, 2010, we recognized as revenue $9.9 million of ARCALYST® (rilonacept) net product sales, which included $5.1 million of ARCALYST® (rilonacept) net product sales made during the quarter and $4.8 million of previously deferred net product sales. For the three months ended March 31, 2009, we recognized as revenue $3.9 million of ARCALYST® (rilonacept) net product sales. There was no deferred ARCALYST® (rilonacept) net product sales revenue at March 31, 2010. At March 31, 2009, deferred ARCALYST® (rilonacept) net product sales revenue was $4.2 million.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended March 31, 2010 and 2009 included $1.1 million and $1.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $132.2 million in the first quarter of 2010 from $92.1 million in the first quarter of 2009. Our average headcount increased to 1,087 in the first quarter of 2010 from 938 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first quarter of 2010 and 2009 include a total of $8.8 million and $7.7 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended March 31, 2010		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 112.5	$ 5.0	$ 117.5
Selling, general, and administrative	10.2	3.8	14.0
Cost of goods sold	0.7		0.7
Total operating expenses	$ 123.4	$ 8.8	$ 132.2

	For the three months ended March 31, 2009		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 75.6	$ 4.7	$ 80.3
Selling, general, and administrative	8.4	3.0	11.4
Cost of goods sold	0.4		0.4
Total operating expenses	$ 84.4	$ 7.7	$ 92.1

Research and Development Expenses

Research and development expenses increased to $117.5 million in the first quarter of 2010 from $80.3 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2010 and 2009:

Research and Development Expenses	For the three months ended March 31,		
(In millions)	2010	2009	Increase
Payroll and benefits (1)	$ 27.7	$ 22.9	$ 4.8
Clinical trial expenses	32.2	19.3	12.9
Clinical manufacturing costs (2)	20.0	14.1	5.9
Research and other development costs	12.8	8.4	4.4
Occupancy and other operating costs	12.0	8.6	3.4
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	12.8	7.0	5.8
Total research and development	$ 117.5	$ 80.3	$ 37.2

(1) Includes $4.3 million and $4.0 million of Non-cash Compensation Expense for the three months ended March 31, 2010 and 2009, respectively.
(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million of Non-cash Compensation Expense for both the three months ended March 31, 2010 and 2009.
(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, DA VINCI trial in DME, and COPERNICUS trial in CRVO, (ii) rilonacept, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of monoclonal antibodies and rilonacept. Research and other development costs increased primarily due to higher costs associated with VEGF Trap-Eye and our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the three months ended March 31,		Increase
(In millions)	2010	2009	(Decrease)
Rilonacept	$ 20.1	$ 17.9	$ 2.2
VEGF Trap-Eye	33.6	20.8	12.8
Aflibercept	3.9	4.2	(0.3)
REGN88	4.9	9.0	(4.1)
Other antibody candidates in clinical development	24.1	4.9	19.2
Other research programs & unallocated costs	30.9	23.5	7.4
Total research and development expenses	$ 117.5	$ 80.3	37.2

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of rilonacept, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® (rilonacept) for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $14.0 million in the first quarter of 2010 from $11.4 million in the same period of 2009. In the first quarter of 2010, we incurred (i) higher compensation expense due primarily to higher Non-cash Compensation Expense and increases in headcount, (ii) higher recruitment costs, and (iii) higher facility-related costs due primarily to our new and expanded leased facilities in Tarrytown, New York and higher headcount.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® (rilonacept) sales, which consisted primarily of royalties and other period costs, totaled $0.7 million and $0.4 million for the quarters ended March 31, 2010 and 2009, respectively. To date, ARCALYST® (rilonacept) shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® (rilonacept) in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $0.4 million in the first quarter of 2010 from $1.8 million in the comparable quarter of 2009, primarily due to lower yields on, and lower balances of, cash and marketable securities and a $0.1 million other-than-temporary impairment charge. Interest expense of $2.1 million in the first quarter of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Income Tax Expense

In accordance with authoritative guidance issued by the Financial Accounting Standards Board (FASB), changes in our unrealized gain on marketable securities, which is included in Accumulated Other Comprehensive Income in the Stockholders' Equity section of our condensed balance sheet, are recognized net of their tax effect. In the first quarter of 2010, we recognized an income tax benefit of $0.2 million in Accumulated Other Comprehensive Income in connection with a decrease in our unrealized gain on marketable securities for the three months ended March 31, 2010. As a result, we recognized $0.2 million of income tax expense in our condensed statement of operations.

Revision of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

As previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009, we revised our previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which we are leasing and to adjust our previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability). We also revised our statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities. In addition, our statement of cash flows for the quarter ended March 31, 2009 was revised to reclassify, from an operating activity to a financing activity, a $5.2 million reimbursement received from our landlord for tenant improvement costs that we incurred. Under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation.

The above described revisions consisted entirely of non-cash adjustments. They had no impact on our business operations, existing capital resources, or our ability to fund our operating needs. The revisions also had no impact on our previously reported net increases or decreases in cash and cash equivalents. In addition, these revisions had no impact on our previously reported current assets, current liabilities, and operating revenues. We did not amend previously issued financial statements because, after considering both qualitative and quantitative factors, we determined that the judgment of a reasonable person relying on our previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to the statement of operations, statement of stockholders' equity, and statement of cash flows for the three months ended March 31, 2009 is as follows:

Statement of Operations Impact for the three months ended March 31, 2009
(In millions, except per share data)

	As Originally Reported	As Revised
Research and development expenses	$ 82.1	$ 80.3
Selling, general, and administrative	11.7	11.4
Total expenses	94.2	92.1
Net loss	(17.5)	(15.4)
Net loss per share, basic and diluted	$ (0.22)	$ (0.19)

Statement of Stockholders' Equity Impact for the three months ended March 31, 2009
(In millions)

	As Originally Reported	As Revised
Accumulated deficit	$ (693.4)	$ (687.7)
Total stockholders' equity	$ 410.3	$ 415.1

Statement of Cash Flows Impact for the three months ended March 31, 2009
(In millions)

	As Originally Reported	As Revised
Net cash used in operating activities	$ (10.2)	$ (15.4)
Net cash used in investing activities	(39.5)	(39.5)
Net cash provided by financing activities	1.0	6.2
Net decrease in cash and cash equivalents	$ (48.7)	$ (48.7)

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® (rilonacept) product revenue, and investment income.

Three months ended March 31, 2010 and 2009

At March 31, 2010, we had $413.5 million in cash, cash equivalents, restricted cash, and marketable securities compared with $390.0 million at December 31, 2009. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York, and a $20.0 million annual technology licensing payment from AstraZeneca.

Cash Used in Operations:

Net cash used in operations was $10.0 million in the first quarter of 2010 and $15.4 million in the first quarter of 2009. Our net losses of $30.5 million in the first quarter of 2010 and $15.4 million in the first quarter of 2009 included $8.8 million and $7.7 million, respectively, of Non-cash Compensation Expense, and $4.2 million and $2.7 million, respectively, of depreciation and amortization.

At March 31, 2010, accounts receivable increased by $6.3 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. At March 31, 2010, accounts payable, accrued expenses, and other liabilities increased by $12.3 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses and payroll and related costs.

At March 31, 2009, accounts receivable increased by $13.0 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by $8.6 million at March 31, 2009, compared to end-of-year 2008, due primarily to higher prepaid clinical trial costs. At March 31, 2009, accounts payable, accrued expenses, and other liabilities increased by $8.0 million, compared to end-of-year 2008, primarily due to higher liabilities for clinical-related expenses and payroll and related costs, which were partially offset by a lower cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration.

Cash Used in Investing Activities:

Net cash used in investing activities was $136.0 million in the first quarter of 2010 and $39.5 million in the first quarter of 2009. In the first quarter of 2010 and 2009, purchases of marketable securities exceeded sales or maturities by $113.2 million and 17.6 million, respectively. Capital expenditures in the first quarter of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

Cash Provided by Financing Activities:

Net cash provided by financing activities was $56.2 million in the first quarter of 2010 and $6.2 million in the first quarter of 2009. In the first quarter of 2010 and 2009, we received $47.5 million and $5.2 million, respectively, from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $9.2 million in the first quarter of 2010 and $1.0 million in the first quarter of 2009.

Fair Value of Marketable Securities:

At March 31, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled $294.6 million and $181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2010		December 31, 2009	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$ 59.2	20%	$ 80.4	44%
U.S. government agency securities	150.0	51%	29.6	16%
U.S. government-guaranteed corporate bonds	64.3	22%	48.7	27%
U.S. government guaranteed collateralized mortgage obligations	3.3	1%	3.7	2%
Corporate bonds	8.2	3%	10.3	6%
Mortgage-backed securities	2.6	1%	3.2	2%
Equity security	4.8	1%	5.4	3%
Other	2.2	1%		
Total marketable securities	$ 294.6	100%	$ 181.3	100%

In addition, at March 31, 2010 and December 31, 2009, we had $118.9 million and $208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled $22.7 million and $21.9 million for the first three months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately $60 to $90 million during the remainder of 2010 and approximately $40 to $60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. We also expect to be reimbursed for a portion of the capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including rilonacept, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® (rilonacept) for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® (rilonacept) for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a $1.6 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In March 2009, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We are required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $1.6 million decrease in the fair value of our investment portfolio at both March 31, 2010 and 2009.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and the first three months of 2010, respectively.

The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2010, we had a cumulative loss of $971.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing rilonacept or VEGF Trap-Eye, or for the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of March 31, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled $413.5 million and represented 53% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $294.6 million at March 31, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and the first three months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and rilonacept in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd line metastatic colorectal cancer, 1st line androgen independent prostate cancer, and 2nd line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

Rilonacept is in Phase 3 clinical trials for two different gout indications – the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that rilonacept will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of rilonacept in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could harm the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® (rilonacept) in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® (rilonacept) may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST® (rilonacept) affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® (rilonacept) may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST® (rilonacept). These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® (rilonacept). Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® (rilonacept) in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® (rilonacept) in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST® (rilonacept). Nineteen of 55 subjects (35%) who received ARCALYST® (rilonacept) for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® (rilonacept) for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® (rilonacept) and the Europeans Medicines Agency approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® (rilonacept) or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® (rilonacept) that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and were included in health care reform legislation recently enacted by the federal government. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the U.S. of health care reform, potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® (rilonacept) and many other related activities in connection with the commercialization of ARCALYST® (rilonacept) for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® (rilonacept) for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® (rilonacept) and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® (rilonacept) and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST® (rilonacept) and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® (rilonacept) or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® (rilonacept) for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009 we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® (rilonacept) in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and Simponi™ (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize rilonacept in other indications and this is one of the reasons we discontinued the development of rilonacept in adult rheumatoid arthritis. In addition, even if rilonacept is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over rilonacept, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST® (rilonacept). For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST® (rilonacept). The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST® (rilonacept).

We have plans to develop rilonacept for the treatment of certain gout indications. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over rilonacept in gout by some physicians, which would make it difficult for us to successfully commercialize rilonacept in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize rilonacept in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have initiated a Phase 3 program studying the use of rilonacept for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® (rilonacept) in the United States for the treatment of a group of rare genetic disorders called CAPS. We recently received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept). Physicians may not prescribe ARCALYST® (rilonacept), and CAPS patients may not be able to afford ARCALYST® (rilonacept), if third party payers do not agree to reimburse the cost of ARCALYST® (rilonacept) therapy and this would adversely affect our ability to commercialize ARCALYST® (rilonacept) profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. The U.S. Congress recently enacted legislation to reform the health care system. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® (rilonacept) and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 14, 2010, our six largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. As of April 14, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.6% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 14, 2010, holders of Class A Stock held 21.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 14, 2010:

- our current executive officers and directors beneficially owned 13.7% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010, and 28.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. In addition, these seven shareholders held 56.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 14, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1(a)	- Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: April 29, 2010

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2010

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2010

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
April 29, 2010

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
April 29, 2010

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 7/28/2010

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2010

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York (Address of principal executive offices)	10591-6707 (Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer __

Non-accelerated filer __ (Do not check if a smaller reporting company) Smaller reporting company __

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes _____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of July 15, 2010:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,182,036
Common Stock, $0.001 par value	79,931,305

REGENERON PHARMACEUTICALS, INC.
Table of Contents
June 30, 2010

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at June 30, 2010 and December 31, 2009	3
	Condensed statements of operations (unaudited) for the three and six months ended June 30, 2010 and 2009	4
	Condensed statements of stockholders' equity (unaudited) for the six months ended June 30, 2010 and 2009	5
	Condensed statements of cash flows (unaudited) for the six months ended June 30, 2010 and 2009	6
	Notes to condensed financial statements (unaudited)	7-13
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	14-37
Item 3	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4	Controls and Procedures	37-38
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	38
Item 1A	Risk Factors	38-54
Item 6	Exhibits	54
SIGNATURE PAGE		55

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT JUNE 30, 2010 AND DECEMBER 31, 2009 (Unaudited)
(In thousands, except share data)

ASSETS	June 30, 2010	December 31, 2009
Current assets:		
Cash and cash equivalents	$ 112,000	$ 207,075
Marketable securities	194,337	134,255
Accounts receivable from the sanofi-aventis Group	91,126	62,703
Accounts receivable - other	4,070	2,885
Prepaid expenses and other current assets	16,217	18,610
Total current assets	417,750	425,506
Restricted cash	3,400	1,600
Marketable securities	70,465	47,080
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	292,329	259,676
Other assets	6,697	7,338
Total assets	$ 790,641	$ 741,202
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 58,256	$ 49,031
Deferred revenue from sanofi-aventis, current portion	19,126	17,523
Deferred revenue - other, current portion	41,741	27,021
Facility lease obligations, current portion	448	
Total current liabilities	119,571	93,575
Deferred revenue from sanofi-aventis	96,168	90,933
Deferred revenue - other	42,009	46,951
Facility lease obligations	157,359	109,022
Other long term liabilities	4,318	3,959
Total liabilities	419,425	344,440
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,182,036 in 2010 and 2,244,698 in 2009	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 79,923,216 in 2010 and 78,860,862 in 2009	80	79
Additional paid-in capital	1,368,531	1,336,732
Accumulated deficit	(997,091)	(941,095)
Accumulated other comprehensive (loss) income	(306)	1,044
Total stockholders' equity	371,216	396,762
Total liabilities and stockholders' equity	$ 790,641	$ 741,202

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Revenues				
Sanofi-aventis collaboration revenue	$ 84,941	$ 60,732	$ 153,612	$ 110,392
Other collaboration revenue	13,635	12,846	26,722	22,794
Technology licensing	10,037	10,000	20,075	20,000
Net product sales	5,197	4,560	15,049	8,391
Contract research and other	2,076	1,954	3,962	3,436
	115,886	90,032	219,420	165,013
Expenses				
Research and development	124,526	94,231	241,997	174,538
Selling, general and administrative	14,679	11,632	28,902	23,052
Cost of goods sold	405	435	1,122	827
	139,610	106,298	272,021	198,417
Loss from operations	(23,724)	(16,266)	(52,601)	(33,404)
Other income (expense)				
Investment income	592	1,328	1,031	3,078
Interest expense	(2,342)		(4,426)	
	(1,750)	1,328	(3,395)	3,078
Net loss	$ (25,474)	$ (14,938)	$ (55,996)	$ (30,326)
Net loss per share, basic and diluted	$ (0.31)	$ (0.19)	$ (0.69)	$ (0.38)
Weighted average shares outstanding, basic and diluted	81,492	79,628	81,330	79,562

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the six months ended June 30, 2010 and 2009
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehe
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2009	2,248	$ 2	76,861	$ 76	$ 1,296,759	$ (941,085)	$ 1,014	$ 356,766	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			878	1	11,391			11,392	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867			2,867	
Issuance of restricted Common Stock under Long-Term Incentive Plan			10						
Conversion of Class A Stock to Common Stock	(59)		54						
Stock-based compensation expense					17,541			17,541	
Net loss						(55,936)		(55,936)	$ (5
Change in net unrealized gain (loss) on marketable securities							(1,350)	(1,350)	
Balance, June 30, 2010	2,189	$ 2	78,913	$ 80	$ 1,328,558	$ (997,021)	$ (336)	$ 331,283	$ (5
Balance, December 31, 2008	2,249	$ 2	77,642	$ 78	$ 1,294,813	$ (872,765)	$ (114)	$ 421,914	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			196		1,705			1,705	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock-based compensation expense					15,094			15,094	
Net loss						(30,326)		(30,326)	$ (3
Change in net unrealized gain (loss) on marketable securities							1,128	1,128	
Balance, June 30, 2009	2,247	$ 2	77,921	$ 78	$ 1,313,003	$ (903,091)	$ 1,014	$ 410,906	$ (3

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Six months ended June 30, 2010	2009
Cash flows from operating activities		
Net loss	$ (55,996)	$ (30,326)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	8,707	5,722
Non-cash compensation expense	17,541	15,094
Other non-cash charges and expenses	225	
Net realized loss on marketable securities	200	
Changes in assets and liabilities		
Increase in accounts receivable	(29,628)	(21,834)
Decrease (increase) in prepaid expenses and other assets	1,604	(578)
Increase in deferred revenue	16,616	5,873
Increase in accounts payable, accrued expenses, and other liabilities	18,105	13,045
Total adjustments	33,370	14,322
Net cash used in operating activities	(22,626)	(16,004)
Cash flows from investing activities		
Purchases of marketable securities	(222,168)	(105,315)
Sales or maturities of marketable securities	137,909	190,723
Capital expenditures	(45,324)	(52,671)
(Increase) decrease in restricted cash	(1,800)	50
Net cash (used in) provided by investing activities	(131,383)	32,787
Cash flows from financing activities		
Proceeds in connection with facility lease obligations	47,544	5,182
Payments in connection with facility lease obligations	(674)	
Net proceeds from the issuance of Common Stock	12,064	1,705
Net cash provided by financing activities	58,934	6,887
Net (decrease) increase in cash and cash equivalents	(95,075)	23,670
Cash and cash equivalents at beginning of period	207,075	247,798
Cash and cash equivalents at end of period	$ 112,000	$ 271,468

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2009 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, was extended. The effect of this change in estimate was to lower depreciation expense by $1.0 million and $2.0 million and to lower the Company's net loss per share by $0.01 and $0.02 for the three and six months ended June 30, 2010, respectively.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010.

ARCALYST® net product sales totaled $5.2 million and $4.5 million for the three months ended June 30, 2010 and 2009, respectively, and $15.0 million and $8.4 million for the six months ended June 30, 2010 and 2009, respectively. ARCALYST® net product sales during the first six months of 2010 included $10.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at June 30, 2010. At June 30, 2009, deferred ARCALYST® net product sales revenue was $4.9 million. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 for the six months ended June 30, 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.4 million for both the three months ended June 30, 2010 and 2009, and $1.1 million and $0.8 million for the six months ended June 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST®; therefore, the costs of these supplies were not included in costs of goods sold. At both June 30, 2010 and December 31, 2009, the Company had $0.4 million of inventoried work-in-process costs related to ARCALYST®, which is included in prepaid expenses and other current assets.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended June 30,	
	2010	2009
Net loss (Numerator)	$ (25,774)	$ (14,958)
Weighted average shares, in thousands (Denominator)	81,492	79,628
Basic and diluted net loss per share	$ (0.31)	$ (0.19)

	Six Months Ended June 30,	
	2010	2009
Net loss (Numerator)	$ (55,998)	$ (30,326)
Weighted average shares, in thousands (Denominator)	81,330	79,562
Basic and diluted net loss per share	$ (0.69)	$ (0.38)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the June 30, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30,	
	2010	2009
Stock Options:		
Weighted average number, in thousands	21,288	20,106
Weighted average exercise price	$ 18.67	$ 17.56
Restricted Stock:		
Weighted average number, in thousands	510	500

	Six months ended June 30,	
	2010	2009
Stock Options:		
Weighted average number, in thousands	21,344	20,161
Weighted average exercise price	$ 18.64	$ 17.56
Restricted Stock:		
Weighted average number, in thousands	506	500

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2010 and December 31, 2009 were $4.1 million and $9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2009 and December 31, 2008 were $12.1 million and $7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were $2.6 million and $1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of $1.3 million for the six months ended June 30, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at June 30, 2010 was $1.7 million of capitalized and deferred interest for the six months ended June 30, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at December 31, 2009 was $0.7 million due to the Company in connection with employee exercises of stock options.

Included in marketable securities at June 30, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2009 and December 31, 2008 were $1.3 million and $1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at June 30, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and an equity security, the aggregate fair value of which was $3.8 million and $5.5 million at June 30, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was $4.0 million at both June 30, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at June 30, 2010 and December 31, 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

At June 30, 2010	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Maturities within one year					
U.S. government obligations	$ 156,142	$156,208	$ 70	$ (4)	$ 66
U.S. government guaranteed corporate bonds	31,216	31,362	148		148
Corporate bonds	3,053	3,067	14		14
Mortgage-backed securities	773	707		(66)	(66)
U.S. government guaranteed collateralized mortgage obligations	2,803	2,993	190		190
	193,987	194,337	420	(70)	350
Maturities between one and four years					
U.S. government obligations	30,476	30,536	60		60
U.S. government guaranteed corporate bonds	32,240	32,648	408		408
Mortgage-backed securities	1,450	1,313		(137)	(137)
Municipal bonds	2,196	2,192	3	(7)	(4)
	66,362	66,689	471	(144)	327
	$ 260,349	$261,026	$ 891	$ (214)	$ 677
At December 31, 2009					
Maturities within one year					
U.S. government obligations	$ 100,491	$100,573	$ 82		$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
Mortgage-backed securities	2,471	2,338		$ (133)	(133)
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
	133,892	134,255	496	(133)	363
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,645	41,611	280	(314)	(34)
	$ 175,537	$175,866	$ 776	$ (447)	$ 329

At June 30, 2010 and December 31, 2009, marketable securities included an additional unrealized loss of $0.3 million and an additional unrealized gain of $1.4 million, respectively, related to the equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at June 30, 2010 and December 31, 2009. The debt securities listed at June 30, 2010 mature at various dates through July 2013.

	Less than 12 Months		12 Months or Greater		Total	
At June 30, 2010	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government obligations	$ 23,417	$ (4)			$ 23,417	$ (4)
Mortgage-backed securities			$ 2,020	$ (203)	2,020	(203)
Municipal bonds	1,188	(7)			1,188	(7)
Equity security	3,776	(268)			3,776	(268)
	$ 28,381	$ (279)	$ 2,020	$ (203)	$ 30,401	$ (482)
At December 31, 2009						
U.S. government obligations	$ 9,367	$ (46)			$ 9,367	$ (46)
Mortgage-backed securities			$ 3,238	$ (401)	3,238	(401)
	$ 9,367	$ (46)	$ 3,238	$ (401)	$ 12,605	$ (447)

Realized gains and losses are included as a component of investment income. For the three and six months ended June 30, 2010 and 2009, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at June 30, 2010 and December 31, 2009, were as follows:

		Fair Value Measurements at Reporting Date Using		
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At June 30, 2010				
Available-for-sale marketable securities				
U.S. government obligations	$ 166,744		$ 166,744	
U.S. government guaranteed corporate bonds	64,010		64,010	
Corporate bonds	3,067		3,067	
Mortgage-backed securities	2,020		2,020	
U.S. government guaranteed collateralized mortgage obligations	2,993		2,993	
Municipal bonds	2,192		2,192	
Equity security	3,776	$ 3,776		
	$ 264,802	$ 3,776	$ 261,026	
At December 31, 2009				
Available-for-sale marketable securities				
U.S. government obligations	$ 109,940		$ 109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
Mortgage-backed securities	3,238		3,238	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Equity security	5,469	$ 5,469		
	$ 181,335	$ 5,469	$ 175,866	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the six months ended June 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the carrying value of the security. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended June 30, 2010, and the three and six months ended June 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At June 30, 2009 and December 31, 2008, the Company held one Level 3 marketable security whose fair value was $0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which took into consideration the securities' lack of liquidity. During the three and six months ended June 30, 2009, the Company did not record any settlements, realized gains or losses, or charges for other-than-temporary impairment related to this Level 3 marketable security. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and six months ended June 30, 2010 and 2009. The Company held no Level 3 marketable securities at June 30, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and six months ended June 30, 2010 and 2009.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment, the deterioration in the credit quality of issuers of securities that the Company holds, and the continuing volatility of securities markets increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2010 and December 31, 2009 consist of the following:

	June 30, 2010	December 31, 2009
Accounts payable	$ 15,325	$ 18,638
Accrued payroll and related costs	19,469	9,444
Accrued clinical trial expense	16,141	11,673
Accrued property, plant, and equipment expenditures	2,041	1,883
Accrued expenses, other	3,080	6,207
Payable to Bayer HealthCare		1,186
	$ 56,056	$ 49,031

7. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and six months ended June 30, 2010 and 2009, the components of comprehensive loss are:

	Three months ended June 30,	
	2010	2009
Net loss	$ (25,474)	$ (14,938)
Change in net unrealized gain (loss) on marketable securities	(1,023)	2,262
Total comprehensive loss	$ (26,497)	$ (12,676)

	Six months ended June 30,	
	2010	2009
Net loss	$ (55,996)	$ (30,328)
Change in net unrealized gain (loss) on marketable securities	(1,350)	1,128
Total comprehensive loss	$ (57,346)	$ (29,198)

8. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

9. Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will be required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

10. Subsequent Event- Extension of Technology Licensing Agreement with Astellas

In March 2007, the Company entered into a six-year non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a $165.0 million up-front payment to the Company. In addition, Astellas will make a $130.0 million payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate this license agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its payment to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune*® technology.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of eye diseases in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondilitis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis; and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite™* technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene®* technology to understand the role of these proteins in normal physiology as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune®*) and cell line expression technologies (*VelociMab®*) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials were developed using *VelocImmune®*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

We and Astellas Pharma Inc. announced in July 2010 that Astellas has extended through 2023 the non-exclusive license agreement that allows Astellas to utilize our *VelocImmune®* technology in its internal research programs to discover fully human monoclonal antibody product candidates. Astellas will pay $165.0 million up-front and another $130.0 million in June 2018 unless it terminates the agreement prior to that date. Upon commercialization of any antibody products discovered utilizing *VelocImmune®*, Astellas will pay us a mid-single-digit royalty on product sales.

Commercial Product:

ARCALYST®– Cryopyrin-Associated Periodic Syndromes (CAPS)

Net product sales of ARCALYST® Injection for Subcutaneous Use in the second quarter of 2010 were $5.2 million, compared to $4.5 million during the same period of 2009. We recognized $15.0 million of net product sales during the first six months of 2010, which included $10.2 million of ARCALYST® net product sales made during the first half of 2010 and $4.8 million of previously deferred net product sales, as described below under "Results of Operations." In the first six months of 2009, we recognized $8.4 million of ARCALYST® net product sales. ARCALYST® is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. ARCALYST®– Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly with allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST® for the treatment of gout. The program included four clinical trials called PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, SURGE (Study Utilizing Rilonacept in Gout Exacerbations), and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations), each of which are described below.

In June 2010, we announced that our PRE-SURGE 1 study in gout patients initiating allopurinol therapy to lower their uric acid levels showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 milligrams (mg) had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$).

All secondary endpoints of the study were highly positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, $p<0.0001$). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, $p<0.001$).

A total of 241 patients were randomized in PRE-SURGE 1, a North America-based double-blind, placebo-controlled study. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/ discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

In addition, in June 2010, we reported results from a placebo-controlled, Phase 3 study (called SURGE), evaluating pain in patients presenting with an acute gout flare. The results of this study showed that there was no significant benefit from combining ARCALYST® with indomethacin (a non-sterodial anti-inflammatory drug considered the standard of care), as measured by the primary study endpoint of the average intensity of gout pain from 24 to 72 hours after initiation of treatment. Patients treated with indomethacin alone experienced an average reduction in patient-reported pain scores (0 to 4 Likert scale where 0 represents no pain and 4 represents extreme pain) of 1.40 points from baseline compared to an average reduction of 1.55 points from baseline in patients treated with both indomethacin and ARCALYST® (p=0.33). Patients who received ARCALYST® alone experienced an average pain reduction of 0.69 points. Treatment with ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most commonly reported adverse event with ARCALYST® was headache.

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. In addition, the global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 is fully enrolled and RE-SURGE is over 90% enrolled. Data from both studies are expected in early 2011. We own worldwide rights to ARCALYST®.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive tiered royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The multi-tiered royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for gout, type 2 diabetes, and other inflammatory diseases.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD) and central retinal vein occlusion (CRVO). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in the fourth quarter of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of visual impairment. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. COPERNICUS is fully enrolled and GALILEO is over 90% enrolled. Initial data from both studies are anticipated in early 2011.

The Phase 2 DME study, known as DA VINCI (DME And VEGF Trap-Eye: INvestigation of Clinical Impact), is a double-masked, randomized, controlled trial that is evaluating four different dosing regimens of VEGF Trap-Eye versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ($p< 0.01$ for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to $70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for metastatic castration-resistant prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in each trial. Based on projected event rates, (i) an interim analysis of VELOUR at 65% of the prespecified number of events required for the final analysis of overall survival is expected to be conducted by an independent statistician and reviewed by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be reviewed by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR and prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune®* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol through a novel mechanism of action. REGN727 is targeted at inhibiting PCSK9, which results in prevention of the degradation of LDLRs in the liver, thereby facilitating LDL clearance from the systemic circulation leading to lower LDL levels in the blood.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL (bad) cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from the Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation is ongoing in both studies.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested to-date, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation in this study is ongoing. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology that has completed Phase 1 studies, the results of which were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune®* technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

7. REGN668 (Anti-IL-4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL-4R) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune®* antibody that is designed to bind to IL-4R. REGN668, which is being developed in collaboration with sanofi-aventis, has completed a Phase 1 trial in healthy volunteers, and will be initiating a Phase 2 trial in atopic dermatitis in the second half of 2010.

8. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune®* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks. The primary endpoint of this study is safety, and REGN475 was generally well tolerated. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion ($p<0.01$). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 ($p<0.01$). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggests that REGN475 therapy will not be effective in this setting.

At the request of the U.S. Food and Drug Administration (FDA), another pharmaceutical company has suspended its anti-NGF antibody clinical program in osteoarthritis and certain other chronic pain indications. We have responded to FDA requests for information about patients in our REGN475 clinical trials. REGN475 is currently not on clinical hold, and our Phase 2 trials in patients with vertebral fracture pain and chronic pancreatitis pain are ongoing. Our Phase 2 trial in osteoarthritis of the knee has been completed. We will update our plans for REGN475 following feedback from the FDA.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®.* The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune®* and our entire *VelociSuite™* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune®* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

Sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only $130-$140 million of antibody discovery costs, with the balance between that amount and $160 million added to the funding otherwise available to us in 2011-2012. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made $20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of $20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune®* technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made $20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a $165.0 million up-front payment to us. In addition, Astellas will make a $130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate this license agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its payment to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune®* technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received $18.1 million through June 30, 2010 and are entitled to receive an additional $7.2 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Regeneron plans to file an Investigational New Drug Application for REGN910, an antibody to Angiopoietin-2, a novel anti-angiogenesis target, by the end of 2010.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2010, we had a cumulative loss of $997.1 million. In the absence of significant revenues from the commercialization of ARCALYST® or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST®; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2010 and plans over the next 12 months are as follows:

Clinical Program	2010 Events to Date	2010-11 Plans (next 12 months)
ARCALYST® (rilonacept)	• Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2. Both Phase 3 studies are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy • Reported results showing no significant improvement in pain relief from a Phase 3 study (SURGE) evaluating ARCALYST® in the treatment of acute gout flares	• Complete patient enrollment of an additional Phase 3 study (RE-SURGE) and report data from PRE-SURGE 2 and RE-SURGE in early 2011 • If PRE-SURGE 2 and RE-SURGE are successful, file for regulatory approval of ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy by mid-2011
VEGF Trap - Eye	• Completed patient enrollment in the first of two Phase 3 CRVO trials (COPERNICUS) • Reported positive 24-week primary endpoint results from the Phase 2 DME trial	• Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 • Complete patient enrollment in the second Phase 3 CRVO trial (GALILEO) and report initial data from both trials • Report one-year results from the Phase 2 DME trial
Aflibercept (VEGF Trap - Oncology)	• Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer, prostate cancer, and colorectal cancer • Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy	• During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study (VELOUR) in colorectal cancer • Report data from the Phase 3 study (VITAL) in non-small cell lung cancer. • In mid-2011, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study (VENICE) in prostate cancer
Monoclonal Antibodies	• REGN727: Reported interim proof-of-concept data from a Phase 1 study for LDL cholesterol reduction • REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis • REGN88: Reported data from the Phase 1 program in rheumatoid arthritis • REGN475: Reported interim data from the Phase 2 studies in osteoarthritis of the knee and acute sciatica	• REGN727: Report additional data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction • REGN668: Initiate a Phase 2 program in the treatment of atopic dermatitis • REGN475: Report additional data from the Phase 2 study in osteoarthritis of the knee • REGN475: Update clinical plans following feedback from the FDA • Advance additional antibody candidates into clinical development, including REGN910

Results of Operations

Three Months Ended June 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of $25.5 million, or $0.31 per share (basic and diluted), for the second quarter of 2010, compared to a net loss of $14.9 million, or $0.19 per share (basic and diluted) for the second quarter of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher collaboration revenue primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended June 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue:		
Sanofi-aventis	$ 84.9	$60.7
Bayer HealthCare	13.7	12.8
Total collaboration revenue	98.6	73.5
Technology licensing revenue	10.0	10.0
Net product sales	5.2	4.5
Contract research and other revenue	2.1	2.0
Total revenue	$115.9	$90.0

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue *(In millions)*	Three months ended June 30,	
	2010	2009
Aflibercept:		
Regeneron expense reimbursement	$ 3.8	$ 9.2
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total aflibercept	6.3	11.7
Antibody:		
Regeneron expense reimbursement	76.4	45.7
Recognition of deferred revenue related to up-front and other payments	1.8	2.6
Recognition of revenue related to *VelociGene*® agreement	0.4	0.7
Total antibody	78.6	49.0
Total sanofi-aventis collaboration revenue	$ 84.9	$ 60.7

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the second quarter of 2010 compared to same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities. As of June 30, 2010, $37.5 million of the original $105.0 million of up-front payments related to our aflibercept collaboration with sanofi-aventis was deferred and will be recognized as revenue in future periods.

In the second quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of $36.6 million under the discovery agreement and $39.8 million of development costs under the license agreement, compared to $28.3 million and $17.4 million, respectively, in the second quarter of 2009. The higher reimbursement amounts in the second quarter of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' $85.0 million up-front payment, decreased during the second quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $14.3 million was received or receivable from sanofi-aventis as of June 30, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment. As of June 30, 2010, $74.6 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. For the three months ended June 30, 2010 and 2009, we recognized $0.4 million and $0.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue *(In millions)*	Three months ended June 30,	
	2010	2009
Cost sharing of Regeneron VEGF Trap-Eye development expenses	$ 11.2	$ 10.1
Recognition of deferred revenue related to up-front and milestone payments	2.5	2.4
Total Bayer HealthCare collaboration revenue	$ 13.7	$ 12.5

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the second quarter of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our Phase 3 trial in CRVO and Phase 2 trial in DME and higher costs related to VEGF Trap-Eye clinical drug supplies. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of June 30, 2010, $51.9 million of the $75.0 million up-front licensing and $20.0 million milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the second quarter of both 2010 and 2009, we recognized $10.0 million of technology licensing revenue related to these agreements.

Net Product Sales

For the three months ended June 30, 2010, ARCALYST® net product sales were $5.2 million, compared to $4.5 million during the same period in 2009. There was no deferred ARCALYST® net product sales revenue at June 30, 2010. At June 30, 2009, deferred ARCALYST® net product sales revenue was $4.9 million.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended June 30, 2010 and 2009 included $1.2 million and $1.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $139.6 million in the second quarter of 2010 from $106.3 million in the second quarter of 2009. Our average headcount increased to 1,214 in the second quarter of 2010 from 966 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the second quarter of 2010 and 2009 include a total of $8.7 million and $7.4 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

Expenses (In millions)	For the three months ended June 30, 2010		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 119.5	$ 5.0	$ 124.5
Selling, general, and administrative	11.0	3.7	14.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 130.9	$ 8.7	$ 139.6

Expenses (In millions)	For the three months ended June 30, 2009		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 89.5	$ 4.7	$ 94.2
Selling, general, and administrative	9.0	2.7	11.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 98.9	$ 7.4	$ 106.3

Research and Development Expenses

Research and development expenses increased to $124.5 million in the second quarter of 2010 from $94.2 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2010 and 2009:

Research and Development Expenses (In millions)	For the three months ended June 30, 2010	2009	Increase (Decrease)
Payroll and benefits (1)	$ 31.9	$ 23.6	$ 8.3
Clinical trial expenses	28.5	30.2	(1.7)
Clinical manufacturing costs (2)	27.6	13.8	13.8
Research and other development costs	13.8	9.9	3.9
Occupancy and other operating costs	12.7	8.9	3.8
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	10.0	7.8	2.2
Total research and development	$ 124.5	$ 94.2	$ 30.3

(1) Includes $4.2 million and $4.0 million of Non-cash Compensation Expense for the three months ended June 30, 2010 and 2009, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.8 million and $0.7 million of Non-cash Compensation Expense for the three months ended June 30, 2010 and 2009, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our ARCALYST® clinical development program in gout. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the three months ended June 30,		Increase
(In millions)	2010	2009	(Decrease)
ARCALYST®	$ 11.6	$ 15.7	$ (4.1)
VEGF Trap-Eye	31.2	27.0	4.2
Aflibercept	3.0	7.4	(4.4)
REGN88	9.8	8.5	1.3
Other antibody candidates in clinical development	26.2	5.1	21.1
Other research programs & unallocated costs	42.7	30.5	12.2
Total research and development expenses	$ 124.5	$ 94.2	$ 30.3

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $14.7 million in the second quarter of 2010 from $11.7 million in the same period of 2009. In the second quarter of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled $0.4 million for both of the quarters ended June 30, 2010 and 2009. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $0.6 million in the second quarter of 2010 from $1.3 million in the comparable quarter of 2009, primarily due to lower balances of, and lower yields on, cash and marketable securities and a $0.1 million other-than-temporary impairment charge. Interest expense of $2.3 million in the second quarter of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Six Months Ended June 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of $56.0 million, or $0.69 per share (basic and diluted), for the first half of 2010, compared to a net loss of $30.3 million, or $0.38 per share (basic and diluted) for the first half of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher collaboration revenue primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the six months ended June 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	$153.6	$110.4
Bayer HealthCare	26.7	22.8
Total collaboration revenue	180.3	133.2
Technology licensing revenue	20.1	20.0
Net product sales	15.0	8.4
Contract research and other revenue	4.0	3.4
Total revenue	$219.4	$165.0

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue *(In millions)*	Six months ended June 30,	
	2010	2009
Aflibercept:		
Regeneron expense reimbursement	$ 8.7	$ 14.6
Recognition of deferred revenue related to up-front payments	5.0	5.0
Total aflibercept	13.7	19.6
Antibody:		
Regeneron expense reimbursement	135.8	84.1
Recognition of deferred revenue related to up-front and other payments	3.3	5.3
Recognition of revenue related to *VelociGene®* agreement	0.8	1.4
Total antibody	139.9	90.8
Total sanofi-aventis collaboration revenue	$ 153.6	$ 110.4

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first half of 2010 compared to the same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities.

In the first half of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of $63.4 million under the discovery agreement and $72.4 million of development costs under the license agreement, compared to $51.0 million and $33.1 million, respectively, in the first half of 2009. The higher reimbursement amounts in the first half of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' $85.0 million up-front payment, decreased during the first half of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the six months ended June 30, 2010 and 2009, we recognized $0.8 million and $1.4 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue *(In millions)*	Six months ended June 30,	
	2010	2009
Cost sharing of Regeneron VEGF Trap-Eye development expenses	$ 21.8	$ 17.9
Recognition of deferred revenue related to up-front and milestone payments	4.9	4.9
Total Bayer HealthCare collaboration revenue	$ 26.7	$ 22.8

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first half of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our Phase 3 trial in CRVO and Phase 2 trial in DME and higher costs related to VEGF Trap-Eye clinical drug supplies.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first half of both 2010 and 2009, we recognized $20.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® for the treatment of CAPS. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the six months ended June 30, 2010, we recognized as revenue $15.0 million of ARCALYST® net product sales, which included $10.2 million of ARCALYST® net product sales made during the period and $4.8 million of previously deferred net product sales. For the six months ended June 30, 2009, we recognized as revenue $8.4 million of ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the first half of 2010 and 2009 included $2.3 million and $3.0 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $272.0 million in the first half of 2010 from $198.4 million in the same period of 2009. Our average headcount increased to 1,151 in the first half of 2010 from 952 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first half of 2010 and 2009 include a total of $17.5 million and $15.1 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the six months ended June 30, 2010		
Expenses *(In millions)*	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 232.0	$ 10.0	$ 242.0
Selling, general, and administrative	21.4	7.5	28.9
Cost of goods sold	1.1		1.1
Total operating expenses	$ 254.5	$ 17.5	$ 272.0

Expenses (In millions)	For the six months ended June 30, 2009 Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
Research and development	$ 165.1	$ 9.4	$ 174.5
Selling, general, and administrative	17.4	5.7	23.1
Cost of goods sold	0.8		0.8
Total operating expenses	$ 183.3	$ 15.1	$ 198.4

Research and Development Expenses

Research and development expenses increased to $242.0 million in the first half of 2010 from $174.5 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2010 and 2009:

Research and Development Expenses (In millions)	For the six months ended June 30, 2010	2009	Increase
Payroll and benefits (1)	$ 59.6	$ 46.5	$ 13.1
Clinical trial expenses	60.8	49.5	11.3
Clinical manufacturing costs (2)	47.5	27.9	19.6
Research and other development costs	26.6	18.4	8.2
Occupancy and other operating costs	24.7	17.4	7.3
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	22.8	14.8	8.0
Total research and development	$ 242.0	$ 174.5	$ 67.5

(1) Includes $8.5 million and $8.0 million of Non-cash Compensation Expense for the six months ended June 30, 2010 and 2009, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.5 million and $1.4 million of Non-cash Compensation Expense for the six months ended June 30, 2010 and 2009, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO, (ii) ARCALYST®, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the six months ended June 30,		Increase
(In millions)	2010	2009	(Decrease)
ARCALYST®	$ 31.7	$ 33.6	$ (1.9)
VEGF Trap-Eye	64.8	47.8	17.0
Aflibercept	6.9	11.7	(4.8)
REGN88	14.7	17.5	(2.8)
Other antibody candidates in clinical development	50.3	(0.9)	40.3
Other research programs & unallocated costs	73.6	53.9	19.7
Total research and development expenses	$ 242.0	$ 174.5	$ 67.5

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2010 and 2009, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $28.9 million in the first half of 2010 from $23.1 million in the same period of 2009. In the first half of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled $1.1 million and $0.8 million for the six months ended June 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $1.0 million in the first half of 2010 from $3.1 million in the comparable quarter of 2009, primarily due to lower balances of, and lower yields on, cash and marketable securities and a $0.1 million other-than-temporary impairment charge. Interest expense of $4.4 million in the first half of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Six months ended June 30, 2010 and 2009

At June 30, 2010, we had $380.2 million in cash, cash equivalents, restricted cash, and marketable securities compared with $390.0 million at December 31, 2009. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York. In addition, in February and June 2010, we received $20.0 million annual technology licensing payments from AstraZeneca and Astellas, respectively.

Cash Used in Operations:

Net cash used in operations was $22.6 million in the first six months of 2010 and $16.0 million in the first six months of 2009. Our net losses of $56.0 million in the first half of 2010 and $30.3 million in the first half of 2009 included $17.5 million and $15.1 million, respectively, of Non-cash Compensation Expense, and $8.7 million and $5.7 million, respectively, of depreciation and amortization.

At June 30, 2010, accounts receivable increased by $29.6 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at June 30, 2010 increased by $16.6 million, compared to end-of-year 2009, primarily due to (i) the receipt of the $20.0 million payments from AstraZeneca and Astellas, as described above, which were deferred and are being recognized ratably over the ensuing year and (ii) sanofi-aventis' funding of $13.8 million of agreed-upon costs incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment received from sanofi-aventis. These increases were partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At June 30, 2010, accounts payable, accrued expenses, and other liabilities increased by $18.1 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

At June 30, 2009, accounts receivable increased by $24.8 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at June 30, 2009 increased by $5.9 million, compared to end-of-year 2008, primarily due to the receipt of $20.0 million annual payments from AstraZeneca and Astellas in February and June 2009, respectively, which were deferred and recognized ratably over the ensuing year. This increase was partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At June 30, 2009, accounts payable, accrued expenses, and other liabilities increased by $13.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a $9.8 million cost-sharing payment which was due to Bayer HealthCare at December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration; no cost-sharing payment was due to Bayer HealthCare at June 30, 2009.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was $131.4 million in the first six months of 2010 and net cash provided by investing activities was $32.8 million in the first six months of 2009. In the first half of 2010, purchases of marketable securities exceeded sales or maturities by $84.3 million, whereas in the first half of 2009, sales or maturities of marketable securities exceeded purchases by $85.4 million. Capital expenditures in the first half of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

Cash Provided by Financing Activities:

Net cash provided by financing activities was $58.9 million in the first six months of 2010 and $6.9 million in the first six months of 2009. In the first half of 2010 and 2009, we received $47.5 million and $5.2 million, respectively, from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $12.1 million in the first six months of 2010 and $1.7 million in the first six months of 2009.

Fair Value of Marketable Securities:

At June 30, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled $264.8 million and $181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	June 30, 2010		December 31, 2009	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$ 25.0	10%	$ 80.4	44%
U.S. government agency securities	161.7	61%	29.6	16%
U.S. government-guaranteed corporate bonds	64.0	24%	48.7	27%
U.S. government guaranteed collateralized mortgage obligations	3.0	1%	3.7	2%
Corporate bonds	3.1	1%	10.3	6%
Mortgage-backed securities	2.0	1%	3.2	2%
Equity security	3.8	1%	5.4	3%
Other	2.2	1%		
Total marketable securities	$ 264.8	100%	$ 181.3	100%

In addition, at June 30, 2010 and December 31, 2009, we had $115.4 million and $208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. Treasury securities, U.S. government agency obligations, and U.S. government-guaranteed debt. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

Funding of Antibody Discovery Activities under Collaboration with sanofi-aventis

As described above under "Antibody Collaboration and License Agreements," in November 2009, we and sanofi-aventis amended our collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only $130-$140 million of antibody discovery costs, with the balance between that amount and $160 million added to the funding otherwise available to us in 2011-2012. The discovery agreement under the antibody collaboration will expire at the end of 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

Extension of License Agreement with Astellas

As described above under "Antibody Collaboration and License Agreements," in July 2010, the non-exclusive license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a $165.0 million up-front payment to us, and will make a $130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled $45.3 million and $52.7 million for the first six months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately $50 to $70 million during the remainder of 2010 and approximately $40 to $60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded $13.8 million of agreed-upon capital expenditures incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at June 30, 2010. We expect to be reimbursed for a portion of additional capital expenditures in 2010 and 2011 for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including ARCALYST®, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements and our non-exclusive license agreement with Astellas, which was amended in July 2010 as described above, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a $3.4 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We are required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $1.2 million and $0.8 million decrease in the fair value of our investment portfolio at June 30, 2010 and 2009, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and the first six months of 2010, respectively.

The current economic environment, the deterioration in the credit quality of issuers of securities that we hold, and the continuing volatility of securities markets increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2010, we had a cumulative loss of $997.1 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements and our non-exclusive license agreement with Astellas, will enable us to meet operating needs through at least 2013; however, one or more of our *VelocImmune*® licenses or collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, or for the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of June 30, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled $380.2 million and represented 48% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $264.8 million at June 30, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and the first six months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST® in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The IDMC for the VELOUR trial, which is studying aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with chemotherapy, is expected to conduct an interim analysis of the data from this trial in the second half of 2010. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® in gout or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. Recently, another pharmaceutical company that is developing an antibody to NGF announced that it has suspended clinical programs for its agent in patients with osteoarthritis and other chronic use indications at the request of the FDA following a small number of reports of patients experiencing a worsening of osteoarthritis or osteonecrosis leading to joint replacement. Although REGN475 has some differences from this third party antibody, the safety risks reported in clinical trials with this other agent could be risks associated with all antibodies to NGF, including our product candidate. This risk or other complications or side effects could result in the discontinuation or limitation of the further development of REGN475 in osteoarthritis and other pain indications, including as a result of being placed on clinical hold by the FDA.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune®* technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® and the Europeans Medicines Agency approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and were included in health care reform legislation recently enacted by the federal government. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the U.S. of the Patient Protection and Affordable Care Act, or PPCA, potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST® and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis (Genentech), for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. In addition, in June 2010, Lucentis (Genentech) was approved by the FDA for the treatment of macular edema because of a blockage in a retinal vein. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and Simponi™ (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST®.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST® in these diseases.

The successful commercialization of ARCALYST® and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the Patient Protection and Affordable Care Act or PPCA and a related reconciliation bill were signed into law. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 14, 2010, our six largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. As of April 14, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.6% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 14, 2010, holders of Class A Stock held 21.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 14, 2010:

- our current executive officers and directors beneficially owned 13.7% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010, and 28.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. In addition, these seven shareholders held 56.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 14, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1	- Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	- Interactive Data File
101.INS	- XBRL Instance Document
101.SCH	- XBRL Taxonomy Extension Schema
101.CAL	- XBRL Taxonomy Extension Calculation Linkbase
101.LAB	- XBRL Taxonomy Extension Label Linkbase
101.PRE	- XBRL Taxonomy Extension Presentation Linkbase
101.DEF	- XBRL Taxonomy Extension Definition Document

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: July 28, 2010

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

SIXTH AMENDMENT TO LEASE

THIS SIXTH AMENDMENT TO LEASE (this "Sixth Amendment") is entered into as of this 4th day of June, 2010 ("Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment"), that certain Third Amendment to Lease dated as of April 29, 2009 (the "Third Amendment"), that certain Fourth Amendment to Lease dated as of December 3, 2009 (the "Fourth Amendment"), and that certain Fifth Amendment to Lease dated as of February 11, 2010 (the "Fifth Amendment" and, collectively with the Original Lease and the First Amendment, Second Amendment, Third Amendment, Fourth Amendment and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 755, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings", and each a "Building");

B. WHEREAS, Tenant desires to lease from Landlord and Landlord desires to lease to Tenant approximately six thousand eight hundred thirty-eight (6,838) rentable square feet of additional space in the 765 Building, consisting of approximately two thousand six hundred ninety-one (2,691) rentable square feet ("Phase 1", and generally a "Phase") and approximately four thousand one hundred forty-seven (4,147) rentable square feet ("Phase 2", and generally a "Phase"), all as shown on Exhibit A attached hereto (Phase 1 and Phase 2 are collectively referred to herein as the "765 Expansion Premises"); and

C. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Sixth Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Sixth Amendment, is referred to herein as the "Amended Lease."

2. 765 Expansion Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord the 765 Expansion Premises, effective as of Landlord's delivery to Tenant of the applicable Phase thereof. Landlord shall use commercially reasonable efforts to deliver Phase 1 to Tenant on the Execution Date, or as soon as reasonably practicable thereafter, and Phase 2 on or before November 30, 2010. Landlord shall provide Tenant with sixty (60) days prior notice of delivery of Phase 2. The Term for the 765 Expansion Premises shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Upon delivery of Phase 1 to Tenant, the total rentable square feet of space of the Premises located within Building 765 shall be one hundred six thousand eight hundred ninety (106,890) rentable square feet of space and upon delivery of Phase 2 to Tenant the total rentable square feet of space of the Premises located within Building 765 shall be one hundred eleven thousand thirty-seven (111,037) rentable square feet of space.

3. Tenant's Pro Rata Shares. From and after the delivery of Phase 1, (a) the Premises shall be deemed to include Phase 1, (b) Tenant's Pro Rata Share of the 765 Building shall increase from 58.80% to 60.23%, (c) Tenant's Pro Rata Share of the Existing Project shall increase from 23.50% to 23.83%, (d) Tenant's Pro Rata Share of the New Project shall remain at 100%, and (e) Tenant's Pro Rata Share of the Entire Project shall increase from 48.30% to 48.52%. From and after the delivery of Phase 2, (v) the Premises shall be deemed to include the entire 765 Expansion Premises, (w) Tenant's Pro Rata Share of the 765 Building shall increase from 60.32% to 62.48%, (x) Tenant's Pro Rata Share of the Existing Project shall increase from 23.85% to 24.36%, (y) Tenant's Pro Rata Share of the New Project shall remain at 100%, and (z) Tenant's Pro Rata Share of the Entire Project shall increase from 48.54% to 48.88%. Effective as of the delivery of Phase 1, Section 2.2 of the Lease is hereby deleted in its entirety and replaced with the following:

> 2.2 The Premises, the Buildings, and certain related terms are defined as follows. In these definitions, each Rentable Area is expressed in rentable square footage. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under this Lease, including under Section 9.2.

Definition or Provision	Means the Following:
"Premises"	Retained Premises, New Premises, Modified Additional Premises, Swap Premises, 755 Premises, Swing Premises, and Phase 1 (of the 765 Expansion Premises)
"Buildings"	735 Building, 745 Building, 755 Building, 765 Building and 777 Building
Rentable Area of Premises	539,822 square feet
Rentable Area of Buildings	117,935 for 735 Building 111,708 for 745 Building 130,877 for 755 Building 177,203 for 765 Building 311,104 for 777 Building
Rentable Area of Existing Project	751,648
Rentable Area of New Project	360,520

Definition or Provision	Means the Following:
Rentable Area of Entire Project	1,112,168
Tenant's Pro Rata Share of Buildings	100% of 735 Building 100% of 745 Building 100% of 755 Building 60.23% of 765 Building 23.28% of 777 Building
Tenant's Pro Rata Share of the Existing Project (Based on Retained Premises, Modified Additional Premises, Swap Premises, Swing Premises and Phase 1 Premises only)	23.83%
Tenant's Pro Rata Share of the New Project (Based on the New Premises and the 755 Premises)	100%
Tenant's Pro Rata Share of Entire Project	48.52%

Effective as of the delivery of Phase 2, Section 2.2 of the Lease is hereby deleted in its entirety and replaced with the following:

2.2 The Premises, the Buildings, and certain related terms are defined as follows. In these definitions, each Rentable Area is expressed in rentable square footage. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under this Lease, including under Section 9.2.

Definition or Provision	Means the Following:
"Premises"	Retained Premises, New Premises, Modified Additional Premises, Swap Premises, 755 Premises, Swing Premises, and 765 Expansion Premises
"Buildings"	735 Building, 745 Building, 755 Building, 765 Building and 777 Building
Rentable Area of Premises	543,969 square feet
Rentable Area of Buildings	117,935 for 735 Building 111,708 for 745 Building 130,877 for 755 Building 177,203 for 765 Building 311,104 for 777 Building
Rentable Area of Existing Project	751,648
Rentable Area of New Project	360,520

Definition or Provision	Means the Following:
Rentable Area of Entire Project	1,112,168
Tenant's Pro Rata Share of Buildings	100% of 735 Building 100% of 745 Building 100% of 755 Building 62.48% of 765 Building 23.28% of 777 Building
Tenant's Pro Rata Share of the Existing Project (Based on Retained Premises, Modified Additional Premises, Swap Premises, Swing Premises and 765 Expansion Premises only)	24.36%
Tenant's Pro Rata Share of the New Project (Based on the New Premises)	100%
Tenant's Pro Rata Share of Entire Project	48.88%

4. Rent.

a. Basic Annual Rent. Commencing as of the dates set forth below and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the 765 Expansion Premises in accordance with the following schedule (in addition to Rent otherwise due under the Lease) and in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 765 Expansion Premises shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011.

Portion of Premises	Applicable Basic Annual Rent Commencement Date	Rentable s.f. of 765 Expansion Premises	Initial Basic Annual Rent Per Rentable s.f. Annually	Total Annual Basic Annual Rent	Total Monthly
Phase 1	Upon delivery of Phase 1	2,691	$27.00	$72,657 (to be prorated)	$6,054.75
Phase 1 and Phase 2	Upon delivery of Phase 2	6,838	$27.00	$184,626 (to be prorated)	$15,385.50

b. Operating Expenses.

i. In addition to Basic Annual Rent, commencing as of the delivery date of the applicable Phase, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the 765 Expansion Premises, or Phase thereof, delivered to Tenant.

ii. For the avoidance of doubt (i) HVAC for the 765 Expansion Premises, or either Phase thereof, shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the 765 Expansion Premises, or either Phase thereof, shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (in each case, as of the applicable commencement date for each such portion of the Premises).

5. Tenant Improvements. Landlord shall make available to Tenant a tenant improvement allowance equal to One Hundred Seventy Thousand Nine Hundred Fifty Dollars (($170,950), based on Twenty-Five Dollars ($25) per rentable square foot of the 765 Expansion Premises) (the "765 Expansion Allowance"). The 765 Expansion Allowance shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of Article 5 of the Lease, including, without limitation, the Disbursement Conditions, in order to finance improvements to the 765 Expansion Premises consistent with the provisions of the Lease and the Permitted Use (such improvements, the "765 Expansion Improvements"). Tenant shall be responsible for performing and completing the 765 Expansion Improvements. Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the Tenant Improvements, including, without limitation, the 765 Expansion Allowance to the extent disbursed to Tenant, which construction oversight fee may be paid out of the 765 Expansion Allowance.

6. Parking. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces with respect to the 765 Expansion Premises.

7. Termination Option. Tenant shall be entitled to terminate the Lease with respect to the entire 765 Expansion Premises effective as of January 1, 2017; provided that (a) Tenant provides Landlord with no less than nine (9) months' prior written notice and (b) concurrently with such notice, Tenant pays to Landlord an amount equal to One Hundred Twenty-Nine Thousand, Nine Hundred Forty-Two Dollars (($129,942) based on Nineteen Dollars ($19) per rentable square foot of the 765 Expansion Premises). If Tenant timely exercises its option to terminate the Lease with respect to the 765 Expansion Premises, then Tenant shall surrender the applicable Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration. Time is of the essence with respect to the exercise of the termination option granted in this Section.

8. Lease Extension Options. From and after the Execution Date, the first paragraph of Article 44 of the Lease is hereby deleted and replaced with the following:

> 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises, (e) the Swap Premises, (f) the Swing Premises, (g) each full floor of the 755 Premises, and (h) the 765 Expansion Premises. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

9. Condition of Premises. Except as otherwise provided herein, Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the 765 Expansion Premises with respect to the suitability of the same for the conduct of Tenant's business. Tenant acknowledges that (a) it is generally familiar with the condition of the 765 Expansion Premises, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the 765 Expansion Premises in its condition "as is" as of the applicable delivery date. Tenant's taking of possession of the 765 Expansion Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the same were at such time in good, sanitary and satisfactory condition and repair. Notwithstanding the foregoing, Landlord represents and warrants that the Building Systems in the 765 Expansion Premises (and each Phase thereof) are, and will be, as of the applicable commencement date for each Phase thereof, in good working condition and that the 765 Expansion Premises (and each Phase thereof) are adequately serviced by Utilities and other base building services.

10. Insurance. From and after the Execution Date, the provisions of Section 22 of the Lease shall apply to all Buildings in which the Premises are located at any time during the Term.

11. Hazardous Materials. From and after the Execution Date, the second to last sentence of Section 40.1 of the Lease shall be deleted and replaced in its entirety with the following:

> Landlord acknowledges that Tenant shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the Entire Project, in the New Whole Building, in the New Multiple Tenant Building, in the Retained Premises, in the Modified Additional Premises, in the Swap Premises, in the 755 Premises, in the Swing Premises, or in the 765 Expansion Premises caused by Landlord or tenants other than Tenant or by third parties in the Entire Project prior to the Execution Date or after such date, or for environmental conditions or contamination coming from off-site so long as Tenant, Tenant's Affiliates, its permitted sublessees or its agents did not cause or contribute to such environmental conditions or contamination.

12. Broker. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Sixth Amendment, other than Studley ("Broker") on behalf of Tenant, and each agrees to indemnify, defend and hold the other harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with this Sixth Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker, which commission shall be calculated on the rentable square footage of the 765 Expansion Premises only.

13. No Default; Authority; Non-Contravention. Each of Landlord and Tenant represents, warrants and covenants that, to the best of its respective knowledge, neither Landlord nor Tenant is in default of any of its respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both), would constitute a default by either Landlord or Tenant thereunder. Each of Landlord and Tenant further represents, warrants and covenants that it has the full power and authority to execute, deliver and comply with the terms of this Sixth Amendment, and doing so will not conflict with or result in the violation of or default under any provision of any agreement or other instrument to which it is a party.

14. Effect of Amendment. Except as modified by this Sixth Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Sixth Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Sixth Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Sixth Amendment.

15. Miscellaneous. This Sixth Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Sixth Amendment are included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference.

16. Counterparts. This Sixth Amendment may be executed in one or more counterparts that, when taken together, shall constitute one original.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Sixth Amendment to Lease.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By: /s/ Matthew McDevitt
Name: Matthew G. McDevitt
Title: EVP, Real Estate

TENANT:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By: /s/ Murray Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

765 Expansion Premises

[IMAGE]

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 28, 2010

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 28, 2010

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
July 28, 2010

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
July 28, 2010

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 10/28/2010

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2010

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No ____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No ____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer ___

Non-accelerated filer ___ (Do not check if a smaller reporting company) Smaller reporting company ___

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of October 15, 2010:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,181,831

Common Stock, $0.001 par value	80,111,128

REGENERON PHARMACEUTICALS, INC.
Table of Contents
September 30, 2010

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at September 30, 2010 and December 31, 2009	3
	Condensed statements of operations (unaudited) for the three and nine months ended September 30, 2010 and 2009	4
	Condensed statements of stockholders' equity (unaudited) for the nine months ended September 30, 2010 and 2009	5
	Condensed statements of cash flows (unaudited) for the nine months ended September 30, 2010 and 2009	6
	Notes to condensed financial statements (unaudited)	7-13
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	14-38
Item 3	Quantitative and Qualitative Disclosures About Market Risk	38
Item 4	Controls and Procedures	38
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	38
Item 1A	Risk Factors	39-55
Item 6	Exhibits	55
SIGNATURE PAGE		56

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2010 AND DECEMBER 31, 2009 (Unaudited)
(In thousands, except share data)

ASSETS	September 30, 2010	December 31, 2009
Current assets		
Cash and cash equivalents	$ 325,286	$ 207,075
Marketable securities	153,767	134,255
Accounts receivable from the sanofi-aventis Group	79,239	62,703
Accounts receivable - other	3,048	2,865
Prepaid expenses and other current assets	14,379	18,610
Total current assets	575,719	425,508
Restricted cash	3,400	1,600
Marketable securities	37,956	47,080
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	318,498	259,676
Other assets	6,860	7,338
Total assets	$ 942,433	$ 741,202
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 74,976	$ 49,031
Deferred revenue from sanofi-aventis, current portion	19,335	17,523
Deferred revenue - other, current portion	38,888	27,021
Facility lease obligations, current portion	634	
Total current liabilities	133,833	93,575
Deferred revenue from sanofi-aventis	99,726	90,933
Deferred revenue - other	197,139	46,951
Facility lease obligations	158,382	109,022
Other long term liabilities	5,289	3,959
Total liabilities	594,369	344,440
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value, 40,000,000 shares authorized; shares issued and outstanding - 2,181,831 in 2010 and 2,244,698 in 2009	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 80,042,523 in 2010 and 78,860,862 in 2009	80	79
Additional paid-in capital	1,379,123	1,336,732
Accumulated deficit	(1,030,966)	(941,095)
Accumulated other comprehensive (loss) income	(175)	1,044
Total stockholders' equity	348,064	396,762
Total liabilities and stockholders' equity	$ 942,433	$ 741,202

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2010	**2009**	**2010**	**2009**
Revenues				
Sanofi-aventis collaboration revenue	$ 75,583	$ 68,536	$ 229,195	$ 178,928
Other collaboration revenue	13,761	32,153	40,483	54,947
Technology licensing	10,037	10,000	30,112	30,000
Net product sales	4,936	4,973	19,985	13,364
Contract research and other	1,662	1,793	5,624	5,229
	105,979	117,455	325,399	282,468
Expenses				
Research and development	122,043	105,434	364,040	279,972
Selling, general, and administrative	15,658	12,840	44,560	35,892
Cost of goods sold	372	472	1,494	1,299
	138,073	118,746	410,094	317,163
Loss from operations	(32,094)	(1,291)	(84,695)	(34,695)
Other income (expense)				
Investment income	453	857	1,484	3,935
Interest expense	(2,234)	(581)	(6,660)	(581)
	(1,781)	276	(5,176)	3,354
Net loss	$ (33,875)	$ (1,015)	$ (89,871)	$ (31,341)
Net loss per share, basic and diluted	$ (0.41)	$ (0.01)	$ (1.10)	$ (0.39)
Weighted average shares outstanding, basic and diluted	81,638	79,866	81,433	79,663

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the nine months ended September 30, 2010 and 2009
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2009	2,245	$ 2	78,861	$ 79	$ 1,336,732	$ (941,095)	$ 1,044	$ 396,762	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			993	1	13,193			13,194	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,867			2,867	
Issuance of restricted Common Stock under Long-Term Incentive Plan			15						
Conversion of Class A Stock to Common Stock	(63)		63						
Stock-based compensation expense					26,331			26,331	
Net loss						(89,871)		(89,871)	$ (89,871)
Change in net unrealized gain (loss) on marketable securities							(1,219)	(1,219)	(1,219)
Balance, September 30, 2010	2,182	$ 2	80,043	$ 80	$ 1,379,123	$ (1,030,966)	$ (175)	$ 348,064	$ (91,090)
Balance, December 31, 2008	2,249	$ 2	77,642	$ 78	$ 1,294,813	$ (873,265)	$ (114)	$ 421,514	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			518		4,626			4,626	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock-based compensation expense					22,602			22,602	
Net loss						(31,341)		(31,341)	$ (31,341)
Change in net unrealized gain (loss) on marketable securities							3,651	3,651	3,651
Balance, September 30, 2009	2,247	$ 2	78,243	$ 78	$ 1,322,432	$ (904,606)	$ 3,537	$ 422,443	$ (27,690)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30, 2010	2009
Cash flows from operating activities		
Net loss	$ (89,871)	$ (31,341)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	13,601	9,312
Non-cash compensation expense	26,331	22,602
Net realized loss (gain) on marketable securities	242	(56)
Changes in assets and liabilities		
Increase in accounts receivable	(16,719)	(32,554)
Decrease (increase) in prepaid expenses and other assets	3,446	(370)
Increase (decrease) in deferred revenue	172,660	(11,379)
Increase in accounts payable, accrued expenses, and other liabilities	28,353	17,960
Total adjustments	227,914	5,515
Net cash provided by (used in) operating activities	138,043	(25,826)
Cash flows from investing activities		
Purchases of marketable securities	(241,665)	(190,666)
Sales or maturities of marketable securities	230,513	284,934
Capital expenditures	(67,427)	(75,002)
(Increase) decrease in restricted cash	(1,800)	50
Net cash (used in) provided by investing activities	(80,379)	19,316
Cash flows from financing activities		
Proceeds in connection with facility lease obligations	47,544	5,182
Payments in connection with facility lease obligations	(757)	(773)
Net proceeds from the issuance of Common Stock	13,760	4,626
Net cash provided by financing activities	60,547	9,035
Net increase in cash and cash equivalents	118,211	2,525
Cash and cash equivalents at beginning of period	207,075	247,796
Cash and cash equivalents at end of period	$ 325,286	$ 250,321

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2009 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, were extended. The effect of this change in estimate was to lower depreciation expense by $1.0 million and $3.0 million and to lower the Company's net loss per share by $0.02 and $0.04 for the three and nine months ended September 30, 2010, respectively.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010.

ARCALYST® net product sales totaled $4.9 million and $5.0 million for the three months ended September 30, 2010 and 2009, respectively, and $20.0 million and $13.4 million for the nine months ended September 30, 2010 and 2009, respectively. ARCALYST® net product sales during the first nine months of 2010 included $15.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at September 30, 2010. At September 30, 2009, deferred ARCALYST® net product sales revenue was $5.0 million. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 for the nine months ended September 30, 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.4 million and $0.5 million for the three months ended September 30, 2010 and 2009, respectively, and $1.5 million and $1.3 million for the nine months ended September 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® for the treatment of CAPS; therefore, the costs of these supplies were not included in costs of goods sold. At both September 30, 2010 and December 31, 2009, the Company had $0.4 million of inventoried work-in-process costs related to ARCALYST®, which is included in prepaid expenses and other current assets.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and nine months ended September 30, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2010	2009
Net loss (Numerator)	$ (33,875)	$ (1,015)
Weighted-average shares, in thousands (Denominator)	81,638	79,866
Basic and diluted net loss per share	$ (0.41)	$ (0.01)

	Nine Months Ended September 30,	
	2010	2009
Net loss (Numerator)	$ (89,871)	$ (31,341)
Weighted-average shares, in thousands (Denominator)	81,433	79,663
Basic and diluted net loss per share	$ (1.10)	$ (0.39)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the September 30, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2010	2009
Stock Options		
Weighted average number, in thousands	21,265	19,860
Weighted average exercise price	$ 18.76	$ 17.65
Restricted Stock		
Weighted average number, in thousands	511	500

	Nine months ended September 30,	
	2010	2009
Stock Options		
Weighted average number, in thousands	21,317	20,059
Weighted average exercise price	$ 18.67	$ 17.59
Restricted Stock		
Weighted average number, in thousands	507	500

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2010 and December 31, 2009 were $12.0 million and $9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2009 and December 31, 2008 were $10.5 million and $7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were $2.6 million and $1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of $4.0 million for the nine months ended September 30, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at September 30, 2010 was $2.6 million of capitalized and deferred interest for the nine months ended September 30, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at September 30, 2010 and December 31, 2009 was $0.1 million and $0.7 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at September 30, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income. Included in marketable securities at September 30, 2009 and December 31, 2008 were $1.0 million and $1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at September 30, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and an equity security, the aggregate fair value of which was $4.0 million and $5.5 million at September 30, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was $4.0 million at both September 30, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at September 30, 2010 and December 31, 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

At September 30, 2010	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Maturities within one year					
U.S. government obligations	$ 106,140	$106,238	$ 101	$ (3)	$ 98
U.S. government guaranteed corporate bonds	44,054	44,237	183		183
U.S. government guaranteed collateralized mortgage obligations	2,481	2,611	130		130
Mortgage-backed securities	689	681		(8)	(8)
	153,364	153,767	414	(11)	403
Maturities between one and five years					
U.S. government obligations	9,046	9,072	26		26
U.S. government guaranteed corporate bonds	21,502	21,829	327		327
Municipal bonds	2,206	2,202	4	(8)	(4)
Mortgage-backed securities	842	675		(167)	(167)
	33,596	33,778	357	(175)	182
Maturities between five and seven years					
Mortgage-backed securities	182	142		(40)	(40)
	$ 187,142	$187,687	$ 771	$ (226)	$ 545
At December 31, 2009					
Maturities within one year					
U.S. government obligations	$ 100,491	$100,573	$ 82		$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
Mortgage-backed securities	2,471	2,338		$ (133)	(133)
	133,892	134,255	496	(133)	363
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,645	41,611	280	(314)	(34)
	$ 175,537	$175,866	$ 776	$ (447)	$ 329

At December 31, 2009, marketable securities included an additional unrealized gain of $1.4 million related to the equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at September 30, 2010 and December 31, 2009. The debt securities listed at September 30, 2010, excluding mortgage-backed securities, mature at various dates through January 2012. The mortgage-backed securities listed at September 30, 2010 mature at various dates through November 2016.

	Less than 12 Months		12 Months or Greater		Total	
At September 30, 2010	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
U.S. government obligations	$ 12,624	$ (3)			$ 12,624	$ (3)
Municipal bonds	1,193	(8)			1,193	(8)
Mortgage-backed securities			$ 1,489	$ (215)	1,489	(215)
Equity security	4,036	(9)			4,036	(9)
	$ 17,853	$ (20)	$ 1,489	$ (215)	$ 19,342	$ (235)
At December 31, 2009						
U.S. government obligations	$ 9,367	$ (46)			$ 9,367	$ (46)
Mortgage-backed securities			$ 3,238	$ (401)	3,238	(401)
	$ 9,367	$ (46)	$ 3,238	$ (401)	$ 12,605	$ (447)

Realized gains and losses are included as a component of investment income. For the three and nine months ended September 30, 2010 and 2009, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at September 30, 2010 and December 31, 2009, were as follows:

		Fair Value Measurements at Reporting Date Using		
	Fair Value	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
At September 30, 2010				
Available-for-sale marketable securities				
U.S. government obligations	$ 115,310		$ 115,310	
U.S. government guaranteed corporate bonds	66,066		66,066	
U.S. government guaranteed collateralized mortgage obligations	2,611		2,611	
Municipal bonds	2,202		2,202	
Mortgage-backed securities	1,498		1,498	
Equity security	4,036	$ 4,036		
	$ 191,723	$ 4,036	$ 187,687	
At December 31, 2009				
Available-for-sale marketable securities				
U.S. government obligations	$ 109,940		$ 109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Mortgage-backed securities	3,238		3,238	
Equity security	5,469	$ 5,469		

	$ 181,335	$ 5,469	$ 175,866

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the nine months ended September 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the carrying value of the security. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended September 30, 2010, and the three and nine months ended September 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At December 31, 2008, the Company held one Level 3 marketable security whose fair value was $0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which took into consideration the securities' lack of liquidity. During the three and nine months ended September 30, 2009, the Company recorded charges for other-than-temporary impairment of this Level 3 marketable security totaling $0.1 million. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and nine months ended September 30, 2010 and 2009. The Company held no Level 3 marketable securities at September 30, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2010 and 2009.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2010 and December 31, 2009 consist of the following:

	September 30, 2010	December 31, 2009
Accounts payable	$ 22,576	$ 18,638
Accrued payroll and related costs	23,583	9,444
Accrued clinical trial expense	14,213	11,673
Accrued property, plant, and equipment expenditures	8,495	1,883
Accrued expenses, other	6,109	6,207
Payable to Bayer HealthCare		1,186
	$ 74,976	$ 49,031

7. Comprehensive Income (Loss)

Comprehensive income (loss) of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and nine months ended September 30, 2010 and 2009, the components of comprehensive income (loss) are:

	Three months ended September 30,	
	2010	**2009**
Net loss	$ (33,875)	$ (1,015)
Change in net unrealized gain (loss) on marketable securities	131	2,523
Total comprehensive (loss) income	$ (33,744)	$ 1,508

	Nine months ended September 30,	
	2010	**2009**
Net loss	$ (89,871)	$ (31,341)
Change in net unrealized gain (loss) on marketable securities	(1,219)	3,651
Total comprehensive loss	$ (91,090)	$ (27,690)

8. Extension of Technology Licensing Agreement with Astellas

In March 2007, the Company entered into a six-year non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to the Company in August 2010, which was deferred upon receipt and will be recognized as revenue ratably over the seven-year period beginning in mid-2011. In addition, Astellas will make a $130.0 million second payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune*® technology. In connection with the Astellas license agreement, the Company recognized $15.0 million of technology revenue for both the nine months ended September 30, 2010 and 2009. In addition, deferred revenue at September 30, 2010 and December 31, 2009 was $178.7 million and $8.7 million, respectively.

9. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

10. Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

11. Subsequent Event – Public Offering of Common Stock

In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of approximately $174.7 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; VEGF Trap-Eye (aflibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of eye diseases in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis; and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. In addition, we expect to file an IND for REGN910, an antibody to Angiopoietin-2 (ANG2), a novel angiogenesis target in the oncology setting, by the end of 2010. We also plan to initiate clinical trials with two additional antibodies by the end of the year, REGN846 and REGN728. Our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials, as well as REGN910, REGN846, and REGN728, were developed using *VelocImmune*®. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST®– Cryopyrin-Associated Periodic Syndromes (CAPS)

Net product sales of ARCALYST® Injection for Subcutaneous Use in the third quarter of 2010 were $4.9 million, compared to $5.0 million during the same period of 2009. We recognized $20.0 million of net product sales during the first nine months of 2010, which included $15.2 million of ARCALYST® net product sales made during that period and $4.8 million of previously deferred net product sales, as described below under "Results of Operations." In the first nine months of 2009, we recognized $13.4 million of ARCALYST® net product sales. ARCALYST® is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. ARCALYST®– Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly with allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program currently consists of PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations), each of which are described below.

In June 2010, we announced that PRE-SURGE 1 showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients initiating urate-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 milligrams (mg) had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$).

All secondary endpoints of the study were highly positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, $p<0.0001$). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, $p<0.001$).

A total of 241 patients were randomized in PRE-SURGE 1, a North America-based double-blind, placebo-controlled study. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/ discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. The global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 and RE-SURGE are fully enrolled, and we expect to have initial data from both studies by early 2011. We own worldwide rights to ARCALYST®.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive tiered royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The multi-tiered royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is approved to treat CAPS and is in development for gout, type 2 diabetes, and other inflammatory diseases.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD) and central retinal vein occlusion (CRVO). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks. VIEW 1 and VIEW 2 are fully enrolled, and initial data from both studies are expected in the fourth quarter of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. Both studies are fully enrolled, and initial data from both studies are anticipated in the first half of 2011.

The Phase 2 DME study, known as DA VINCI (DME And VEGF Trap-Eye: INvestigation of Clinical Impact), is a double-masked, randomized, controlled trial that is evaluating four different dosing regimens of VEGF Trap-Eye versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ($p < 0.01$ for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results from this trial will be available in the fourth quarter of 2010.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to $70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. Aflibercept (VEGF Trap) – Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in each trial. In September 2010, we and sanofi aventis announced that, following a planned interim analysis, the VELOUR study's IDMC recommended that the VELOUR study continue to completion as planned, with no modifications due to efficacy or safety concerns. Both sanofi-aventis and our management and staff remain blinded to the interim study results. Based on projected event rates, final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR and prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune*® technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol through a novel mechanism of action. REGN727 is targeted at inhibiting PCSK9, which results in prevention of the degradation of LDLRs in the liver, thereby facilitating LDL clearance from the systemic circulation leading to lower LDL levels in the blood.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL (bad) cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation is ongoing in both studies.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported. Dose escalation in this study is ongoing. We expect to begin a Phase 2 program in the first half of 2011. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), Actemra® (tocilizumab), marketed by Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology that has completed Phase 1 studies, the results of which were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune®* technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

7. REGN668 (Anti-IL-4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL-4R) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune®* technology that is designed to bind to IL-4R. REGN668, which is being developed in collaboration with sanofi-aventis, has completed a Phase 1 trial in healthy volunteers, and will be initiating a Phase 2 trial in atopic dermatitis in the fourth quarter of 2010.

8. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune®* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks. The primary endpoint of this study is safety, and REGN475 was generally well tolerated. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion ($p<0.01$). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 ($p<0.01$). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales.

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggests that REGN475 therapy will not be effective in this setting.

At the request of the U.S. Food and Drug Administration (FDA), another pharmaceutical company has suspended its anti-NGF antibody clinical program in osteoarthritis and certain other chronic pain indications. We have responded to FDA requests for information about patients in our REGN475 clinical trials. REGN475 is currently not on clinical hold, and our Phase 2 trials in patients with vertebral fracture pain and chronic pancreatitis pain are ongoing. Our Phase 2 trial in osteoarthritis of the knee has been completed.

9. REGN910 (Anti-ANG2 Antibody) for oncology

We expect to file an IND for REGN910, an antibody to Angiopoietin-2 (ANG2), a novel angiogenesis target in the oncology setting, by the end of 2010. REGN910 is being developed in collaboration with sanofi-aventis.

10. Additional antibody candidates

We plan to initiate clinical trials with two additional antibodies by the end of the year, REGN846 and REGN728, both being developed in collaboration with sanofi-aventis.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®*. The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune®* and our entire *VelociSuite™* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune®* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only $130-$140 million of antibody discovery costs, with the balance between that amount and $160 million added to the funding otherwise available to us in 2011-2012. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made $20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of $20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune®* technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made $20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune®* technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received $19.3 million from the grant's inception through September 30, 2010 and are entitled to receive an additional $6.0 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2010, we had a cumulative loss of $1.0 billion. In the absence of significant revenues from the commercialization of ARCALYST® or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST®; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2010 and plans over the next 12 months are as follows:

Clinical Program	**2010 Events to Date**	**2010-11 Plans (next 12 months)**
ARCALYST® (rilonacept)	• Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2 and RE-SURGE. PRE-SURGE 1 and 2 are Phase 3 studies that are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy • Reported results showing no significant improvement in pain relief from a separate Phase 3 study evaluating ARCALYST® in the treatment of acute gout flares	• Report data from PRE-SURGE 2 and RE-SURGE in early 2011
VEGF Trap – Eye	• Completed patient enrollment in two Phase 3 CRVO trials (COPERNICUS and GALILEO) • Reported positive 24-week primary endpoint results from the Phase 2 DME trial (DA VINCI)	• Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 • Report data from GALILEO and COPERNICUS trials in the first half of 2011 • Report one-year results from the DA VINCI trial in the fourth quarter of 2010
Aflibercept (VEGF Trap – Oncology)	• Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer (VITAL), prostate cancer (VENICE), and colorectal cancer (VELOUR) • Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer (AFFIRM) in combination with chemotherapy • An IDMC conducted an interim analysis of the VELOUR study in colorectal cancer and recommended that the study continue to completion as planned with no modifications due to efficacy or safety concerns	• Report data from the VITAL study in non-small cell lung cancer in the first half of 2011 • An IDMC is expected to conduct an interim analysis of the VENICE study in prostate cancer in mid-2011 • Report data from the VELOUR study in metastatic colorectal cancer in the second half of 2011

Clinical Program	2010 Events to Date	2010-11 Plans (next 12 months)
REGN727 (PCSK9 Antibody)	• Reported proof-of-concept data from a Phase 1 study for LDL cholesterol reduction	• Report additional data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction
REGN88 (IL-6R Antibody)	• Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis • Reported data from the Phase 1 program in rheumatoid arthritis	• Report data from the Phase 2 portion of a Phase 2/3 study in rheumatoid arthritis
REGN421 (Dll4 Antibody)		• Initiate a Phase 2 program in advanced malignancies
REGN668 (IL-4RAntibody)	• Completed a Phase 1 study in healthy volunteers	• Initiate a Phase 2 program in the treatment of atopic dermatitis in the fourth quarter of 2010
REGN475 (NGF Antibody)	• Reported interim data from the Phase 2 studies in osteoarthritis of the knee and acute sciatica	• Report additional data from the Phase 2 study in osteoarthritis of the knee
REGN910 (ANG2 Antibody)	• Completed preclinical development	• Initiate a Phase 1 study in oncology by the end of 2010

Results of Operations

Three Months Ended September 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of $33.9 million, or $0.41 per share (basic and diluted), for the third quarter of 2010, compared to a net loss of $1.0 million, or $0.01 per share (basic and diluted) for the third quarter of 2009. The increase in our net loss was principally due to higher research and development expenses in 2010, as detailed below, as well as a decrease in collaboration revenue due to the receipt of a $20.0 million substantive milestone payment from Bayer HealthCare in 2009.

Revenues

Revenues for the three months ended September 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	$ 75.6	$ 68.5
Bayer HealthCare	13.8	32.2
Total collaboration revenue	89.4	100.7
Technology licensing revenue	10.0	10.0
Net product sales	4.9	5.0
Contract research and other revenue	1.7	1.8
Total revenue	$106.0	$117.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue	Three months ended September 30,	
(In millions)	2010	2009
Aflibercept		
Regeneron expense reimbursement	$ 3.9	$ 7.0
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total aflibercept	6.4	9.5
Antibody		
Regeneron expense reimbursement	66.8	55.7
Recognition of deferred revenue related to up-front and other payments	2.0	2.6
Recognition of revenue related to *VelociGene*® agreement	0.4	0.7
Total antibody	69.2	59.0
Total sanofi-aventis collaboration revenue	$ 75.6	$ 68.5

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the third quarter of 2010 compared to same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities. As of September 30, 2010, $35.0 million of the original $105.0 million of up-front payments related to our aflibercept collaboration with sanofi-aventis was deferred and will be recognized as revenue in future periods.

In the third quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of $36.9 million under the discovery agreement and $29.9 million of development costs under the license agreement, compared to $25.7 million and $30.0 million, respectively, in the third quarter of 2009. The higher reimbursement of our antibody expenses in the third quarter of 2010 compared to the same period in 2009 was due to an increase in our research activities conducted under the discovery agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' $85.0 million up-front payment, decreased during the third quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $21.6 million was received or receivable from sanofi-aventis as of September 30, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment. As of September 30, 2010, $80.0 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. For the three months ended September 30, 2010 and 2009, we recognized $0.4 million and $0.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Three months ended September 30,**	
(In millions)	**2010**	**2009**
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 11.3	$ 9.7
Substantive performance milestone payment		20.0
Recognition of deferred revenue related to up-front and milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 13.8	$ 32.2

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the third quarter of 2010, compared to the same period in 2009, due to higher internal development activities and higher costs related to manufacturing VEGF Trap-Eye clinical supplies. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of September 30, 2010, $49.4 million of the $75.0 million up-front licensing and $20.0 million milestone payments was deferred and will be recognized as revenue in future periods. In July 2009, we received a $20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in other collaboration revenue for the three months ended September 30, 2009.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments have been deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the third quarter of both 2010 and 2009, we recognized $10.0 million of technology licensing revenue related to these agreements. In addition, in connection with the amendment and extension of our license agreement with Astellas, as described above under "Antibody Collaboration and License Agreements," the $165.0 million up-front payment was deferred upon receipt in August 2010 and will be recognized as revenue ratably over a seven-year period beginning in mid-2011.

Net Product Sales

For the three months ended September 30, 2010, ARCALYST® net product sales were $4.9 million, compared to $5.0 million during the same period in 2009. There was no deferred ARCALYST® net product sales revenue at September 30, 2010. At September 30, 2009, deferred ARCALYST® net product sales revenue was $5.0 million.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended September 30, 2010 and 2009 included $1.2 million and $1.4 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $138.1 million in the third quarter of 2010 from $118.7 million in the third quarter of 2009. Our average headcount increased to 1,317 in the third quarter of 2010 from 998 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the third quarter of 2010 and 2009 include a total of $8.8 million and $7.5 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended September 30, 2010		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 116.7	$ 5.3	$ 122.0
Selling, general, and administrative	12.2	3.5	15.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 129.3	$ 8.8	$ 138.1

	For the three months ended September 30, 2009		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 100.8	$ 4.6	$ 105.4
Selling, general, and administrative	9.9	2.9	12.8
Cost of goods sold	0.5		0.5
Total operating expenses	$ 111.2	$ 7.5	$ 118.7

Research and Development Expenses

Research and development expenses increased to $122.0 million in the third quarter of 2010 from $105.4 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2010 and 2009:

	For the three months ended September 30,		Increase
Research and Development Expenses *(In millions)*	**2010**	**2009**	**(Decrease)**
Payroll and benefits (1)	$ 34.7	$ 24.5	$ 10.2
Clinical trial expenses	23.1	29.4	(6.3)
Clinical manufacturing costs (2)	25.1	18.0	7.1
Research and other development costs	13.8	11.1	2.7
Occupancy and other operating costs	13.5	10.5	3.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	11.8	11.9	(0.1)
Total research and development expenses	$ 122.0	$ 105.4	$ 16.6

(1) Includes $4.6 million and $3.9 million of Non-cash Compensation Expense for the three months ended September 30, 2010 and 2009, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.7 million of Non-cash Compensation Expense for both the three months ended September 30, 2010 and 2009.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our ARCALYST® clinical development program in gout and certain monoclonal antibodies which are in earlier stage clinical development. Clinical manufacturing costs increased primarily due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility. In addition, we incurred higher costs related to manufacturing clinical supplies of ARCALYST® and VEGF Trap-Eye, partly offset by lower costs related to manufacturing clinical supplies of monoclonal antibodies and aflibercept. Research and other development costs increased primarily due to higher costs associated with our VEGF Trap-Eye, ARCALYST®, and antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses decreased slightly primarily due to lower costs associated with the VIEW 2 trial in wet AMD which were offset by higher costs in connection with the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**For the three months ended September 30,**		**Increase**
(In millions)	**2010**	**2009**	**(Decrease)**
ARCALYST®	$ 16.5	$ 15.5	$ 1.0
VEGF Trap-Eye	33.2	29.9	3.3
Aflibercept	2.8	6.1	(3.3)
REGN88	6.0	10.0	(4.0)
Other antibody candidates in clinical development	18.4	9.5	8.9
Other research programs & unallocated costs	45.1	34.4	10.7
Total research and development expenses	$ 122.0	$ 105.4	$ 16.6

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $15.7 million in the third quarter of 2010 from $12.8 million in the same period of 2009. In the third quarter of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled $0.4 million and $0.5 million for the quarters ended September 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® for the treatment of CAPS in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $0.5 million in the third quarter of 2010 from $0.9 million in the comparable quarter of 2009, primarily due to lower average balances of, and lower yields on, cash and marketable securities. Interest expense of $2.2 million and $0.6 million in the third quarter of 2010 and 2009, respectively, was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Nine Months Ended September 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of $89.9 million, or $1.10 per share (basic and diluted), for the first nine months of 2010, compared to a net loss of $31.3 million, or $0.39 per share (basic and diluted) for the first nine months of 2009. The increase in our net loss was principally due to higher research and development expenses in 2010, as detailed below, partly offset by higher collaboration revenue in 2010 primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the nine months ended September 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	$229.2	$ 178.9
Bayer HealthCare	40.5	54.9
Total collaboration revenue	269.7	233.8
Technology licensing revenue	30.1	30.0
Net product sales	20.0	13.4
Contract research and other revenue	5.6	5.3
Total revenue	$325.4	$ 282.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue	**Nine months ended September 30,**	
(In millions)	**2010**	**2009**
Aflibercept:		
Regeneron expense reimbursement	$ 12.6	$ 21.6
Recognition of deferred revenue related to up-front payments	7.4	7.4
Total aflibercept	20.0	29.0
Antibody:		
Regeneron expense reimbursement	202.7	139.8
Recognition of deferred revenue related to up-front and other payments	5.3	7.9
Recognition of revenue related to *VelociGene*® agreement	1.2	2.2
Total antibody	209.2	149.9
Total sanofi-aventis collaboration revenue	$ 229.2	$ 178.9

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first nine months of 2010 compared to the same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities.

In the first nine months of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of $100.3 million under the discovery agreement and $102.4 million of development costs under the license agreement, compared to $76.7 million and $63.1 million, respectively, in the first nine months of 2009. The higher reimbursement amounts in the first nine months of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' $85.0 million up-front payment, decreased during the first nine months of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration.

In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. For the nine months ended September 30, 2010 and 2009, we recognized $1.2 million and $2.2 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Nine months ended September 30,**	
(In millions)	**2010**	**2009**
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 33.1	$ 27.5
Substantive performance milestone payment		20.0
Recognition of deferred revenue related to up-front and milestone payments	7.4	7.4
Total Bayer HealthCare collaboration revenue	$ 40.5	$ 54.9

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first nine months of 2010, compared to the same period in 2009, due to higher internal development activities, higher costs related to manufacturing VEGF Trap-Eye clinical supplies, and higher clinical development costs in connection with our Phase 3 trial in CRVO. In July 2009, we received a $20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in other collaboration revenue for the nine months ended September 30, 2009.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments have been deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement In the first nine months of both 2010 and 2009, we recognized $30.0 million of technology licensing revenue related to these agreements. In addition, in connection with the amendment and extension of our license agreement with Astellas, the $165.0 million up-front payment was deferred upon receipt in August 2010 and will be recognized as revenue ratably over a seven-year period beginning in mid-2011.

Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® for the treatment of CAPS. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the nine months ended September 30, 2010, we recognized as revenue $20.0 million of ARCALYST® net product sales, which included $15.2 million of ARCALYST® net product sales made during the period and $4.8 million of previously deferred net product sales. For the nine months ended September 30, 2009, we recognized as revenue $13.4 million of ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the first nine months of 2010 and 2009 included $3.5 million and $4.4 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $410.1 million in the first nine months of 2010 from $317.2 million in the same period of 2009. Our average headcount increased to 1,206 in the first nine months of 2010 from 967 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first nine months of 2010 and 2009 include a total of $26.3 million and $22.6 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the nine months ended September 30, 2010		
Expenses	**Expenses before inclusion of Non-cash Compensation**	**Non-cash Compensation**	**Expenses as**
(In millions)	**Expense**	**Expense**	**Reported**
Research and development	$ 348.7	$ 15.3	$ 364.0
Selling, general, and administrative	33.6	11.0	44.6
Cost of goods sold	1.5		1.5
Total operating expenses	$ 383.8	$ 26.3	$ 410.1

	For the nine months ended September 30, 2009		
Expenses	**Expenses before inclusion of Non-cash Compensation**	**Non-cash Compensation**	**Expenses as**
(In millions)	**Expense**	**Expense**	**Reported**
Research and development	$ 266.0	$ 14.0	$ 280.0
Selling, general, and administrative	27.3	8.6	35.9
Cost of goods sold	1.3		1.3
Total operating expenses	$ 294.6	$ 22.6	$ 317.2

Research and Development Expenses

Research and development expenses increased to $364.0 million in the first nine months of 2010 from $280.0 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2010 and 2009:

Research and Development Expenses	**For the nine months ended September 30,**		
(In millions)	**2010**	**2009**	**Increase**
Payroll and benefits (1)	$ 94.3	$ 71.0	$ 23.3
Clinical trial expenses	83.8	78.9	4.9
Clinical manufacturing costs (2)	72.6	46.0	26.6
Research and other development costs	40.4	29.5	10.9
Occupancy and other operating costs	38.3	27.9	10.4
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	34.6	26.7	7.9
Total research and development expenses	$ 364.0	$ 280.0	$ 84.0

(1) Includes $13.1 million and $11.8 million of Non-cash Compensation Expense for the nine months ended September 30, 2010 and 2009, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $2.2 million of Non-cash Compensation Expense for both the nine months ended September 30, 2010 and 2009.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO, and certain monoclonal antibody candidates, which are in earlier stage clinical development, partly offset by lower costs related to our Phase 3 clinical development program for ARCALYST® in gout. Clinical manufacturing costs increased primarily due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility. In addition, we incurred higher costs related to manufacturing clinical supplies of VEGF Trap-Eye, ARCALYST®, and certain monoclonal antibodies partly offset by lower costs related to manufacturing clinical supplies of aflibercept. Research and other development costs increased primarily due to higher costs associated with our VEGF Trap-Eye, ARCALYST®, and antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**For the nine months ended September 30,**		**Increase**
(In millions)	**2010**	**2009**	**(Decrease)**
ARCALYST®	$ 48.2	$ 49.1	$ (0.9)
VEGF Trap-Eye	98.0	77.7	20.3
Aflibercept	9.8	17.7	(7.9)
REGN88	20.7	27.5	(6.8)
Other antibody candidates in clinical development	68.7	19.4	49.3
Other research programs & unallocated costs	118.6	88.6	30.0
Total research and development expenses	$ 364.0	$ 280.0	$ 84.0

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2010 and 2009, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $44.6 million in the first nine months of 2010 from $35.9 million in the same period of 2009. In the first nine months of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, higher recruitment costs, and higher patent-related costs associated with our monoclonal antibody programs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled $1.5 million and $1.3 million for the nine months ended September 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® for the treatment of CAPS in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to $1.5 million in the first nine months of 2010 from $3.9 million in the comparable period of 2009, primarily due to lower average balances of, and lower yields on, cash and marketable securities and a $0.1 million other-than-temporary impairment charge. Interest expense of $6.7 million and $0.6 million in the first nine months of 2010 and 2009, respectively, was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Nine months ended September 30, 2010 and 2009

At September 30, 2010, we had $520.4 million in cash, cash equivalents, restricted cash, and marketable securities compared with $390.0 million at December 31, 2009. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York. In February and June 2010, we received $20.0 million annual technology licensing payments from both AstraZeneca and Astellas. In August 2010, we received a $165.0 million up-front payment in connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, as described above under "Antibody Collaboration and License Agreements."

Cash Provided by (Used in) Operating Activities:

Net cash provided by operating activities was $138.0 million in the first nine months of 2010 and net cash used in operating activities was $25.8 million in the first nine months of 2009. Our net losses of $89.9 million in the first nine months of 2010 and $31.3 million in the first nine months of 2009 included $26.3 million and $22.6 million, respectively, of Non-cash Compensation Expense, and $13.6 million and $9.3 million, respectively, of depreciation and amortization.

At September 30, 2010, accounts receivable increased by $16.7 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2010 increased by $172.7 million, compared to end-of-year 2009, primarily due to (i) the receipt of the $165.0 million up-front payment from Astellas, as described above, which was deferred and will be recognized ratably over the seven-year period commencing in mid-2011, (ii) the receipt of the $20.0 million payments from AstraZeneca and Astellas, as described above, which were deferred and are being recognized ratably over the ensuing year, and (iii) sanofi-aventis' funding of $21.1 million of agreed-upon costs incurred by us during the first nine months of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment received from sanofi-aventis. These increases were partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At September 30, 2010, accounts payable, accrued expenses, and other liabilities increased by $28.4 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

At September 30, 2009, accounts receivable increased by $32.6 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2009 decreased by $11.4 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the receipt of $20.0 million payments from AstraZeneca and Astellas in February and June 2009, respectively, which were deferred and recognized ratably over the ensuing year. At September 30, 2009, accounts payable, accrued expenses, and other liabilities increased by $18.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a $7.0 million decrease in the cost-sharing payment due to Bayer HealthCare at September 30, 2009 compared to December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was $80.4 million in the first nine months of 2010 and net cash provided by investing activities was $19.3 million in the first nine months of 2009. In the first nine months of 2010, purchases of marketable securities exceeded sales or maturities by $11.2 million, whereas in the first nine months of 2009, sales or maturities of marketable securities exceeded purchases by $94.3 million. Capital expenditures in the first nine months of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

Cash Provided by Financing Activities:

Net cash provided by financing activities was $60.5 million in the first nine months of 2010 and $9.0 million in the first nine months of 2009. In the first nine months of 2010 and 2009, we received $47.5 million and $5.2 million, respectively, from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $13.8 million in the first nine months of 2010 and $4.6 million in the first nine months of 2009.

Fair Value of Marketable Securities:

At September 30, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled $191.7 million and $181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	September 30, 2010		December 31, 2009	
Investment type	**Fair Value**	**Percent**	**Fair Value**	**Percent**
U.S. government agency securities	$ 115.3	60%	$ 29.6	16%
U.S. Treasury securities			80.4	44%
U.S. government-guaranteed corporate bonds	66.1	34%	48.7	27%
U.S. government guaranteed collateralized mortgage obligations	2.6	2%	3.7	2%
Corporate bonds			10.3	6%
Mortgage-backed securities	1.5	1%	3.2	2%
Equity security	4.0	2%	5.4	3%
Other	2.2	1%		
Total marketable securities	$ 191.7	100%	$ 181.3	100%

In addition, at September 30, 2010 and December 31, 2009, we had $328.7 million and $208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. government agency obligations, U.S. government-guaranteed debt, and U.S. Treasury securities. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

Funding of Antibody Discovery Activities under Collaboration with sanofi-aventis

As described above under "Antibody Collaboration and License Agreements," in November 2009, we and sanofi-aventis amended our collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only $130-$140 million of antibody discovery costs, with the balance between that amount and $160 million added to the funding otherwise available to us in 2011-2012. The discovery agreement under the antibody collaboration will expire at the end of 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

Extension of License Agreement with Astellas

As described above under "Antibody Collaboration and License Agreements," in July 2010, the non-exclusive license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010, and will make a $130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date.

Public Offering of Common Stock

In October 2010, the Company completed an underwritten public offering of approximately 6.3 million shares of Common Stock and received net proceeds of approximately $174.7 million. We intend to use the net proceeds from this offering for general corporate purposes.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled $67.4 million and $75.0 million for the first nine months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately $30 to $50 million during the remainder of 2010 and approximately $40 to $70 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded $21.1 million of agreed-upon capital expenditures incurred by us during the first nine months of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at September 30, 2010. We expect to be reimbursed for a portion of additional capital expenditures in 2010 and 2011 for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including ARCALYST®, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to fund costs to commercialize our product candidates, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements and the net proceeds from our October 2010 public offering of Common Stock, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a $3.4 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of September 30, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We will adopt this amended guidance for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $0.4 million and $0.9 million decrease in the fair value of our investment portfolio at September 30, 2010 and 2009, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and the first nine months of 2010, respectively.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2010, we had a cumulative loss of $1.0 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements and the net proceeds from our October 2010 public offering of Common Stock, will enable us to meet operating needs through at least 2013; however, one or more of our *VelocImmune*® licenses or collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, or for the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of September 30, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled $520.4 million and represented 55% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $191.7 million at September 30, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of $2.5 million, $0.1 million, and $0.1 million in 2008, 2009, and the first nine months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the continued volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST® in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® in gout or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. Recently, another pharmaceutical company that is developing an antibody to NGF announced that it has suspended clinical programs for its agent in patients with osteoarthritis and other chronic use indications at the request of the FDA following a small number of reports of patients experiencing a worsening of osteoarthritis or osteonecrosis leading to joint replacement. Although REGN475 has some differences from this third party antibody, the safety risks reported in clinical trials with this other agent could be risks associated with all antibodies to NGF, including our product candidate. This risk or other complications or side effects could result in the discontinuation or limitation of the further development of REGN475 in osteoarthritis and other pain indications, including as a result of being placed on clinical hold by the FDA.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® and the Europeans Medicines Agency approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our marketed product and product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and were included in health care reform legislation recently enacted by the federal government. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;

- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the U.S. of the Patient Protection and Affordable Care Act, or PPACA, potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST® and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis (Genentech), for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. In addition, in June 2010, Lucentis (Genentech) was approved by the FDA for the treatment of macular edema because of a blockage in a retinal vein. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin.

The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. Data from these trials are expected in 2011. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and Simponi™ (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST®.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs will make it difficult for us to successfully commercialize ARCALYST® in these diseases.

The successful commercialization of ARCALYST® and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the Patient Protection and Affordable Care Act, or PPACA, and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2010, our six largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 62.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2010. As of September 30, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.5% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2010, holders of Class A Stock held 21.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2010:

- our current executive officers and directors beneficially owned 13.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2010, and 28.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 62.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2010. In addition, these seven shareholders held 65.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1*	- Amendment to the Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 by and between Astellas Pharma Inc. and the Registrant, dated as of July 28, 2010.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	- Interactive Data File
101.INS	- XBRL Instance Document
101.SCH	- XBRL Taxonomy Extension Schema
101.CAL	- XBRL Taxonomy Extension Calculation Linkbase
101.LAB	- XBRL Taxonomy Extension Label Linkbase
101.PRE	- XBRL Taxonomy Extension Presentation Linkbase
101.DEF	- XBRL Taxonomy Extension Definition Document

* Portions of this document have been omitted and filed separately with the Commission pursuant to a request for confidential treatment pursuant to Rule 24b-2.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: October 28, 2010

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Exhibit 10.1
Portions of this Exhibit Have Been
Omitted and Separately Filed with the Securities
And Exchange Commission with a Request
For Confidential Treatment

Amendment to the Non-Exclusive License
and Material Transfer Agreement
dated as of March 30, 2007

This Amendment ("Amendment"), dated as of July 28, 2010 (the "Amendment Effective Date"), is by and between Astellas Pharma Inc. ("Company"), a Japanese company with a principal place of business located at 2-3-11 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan and Regeneron Pharmaceuticals, Inc. ("Regeneron"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, Company and Regeneron (collectively, the "Parties") entered into a Non-Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 (the "Original Agreement"); and

WHEREAS, the Parties now desire to amend the Original Agreement to extend the term of the Original Agreement and make such other amendments to the terms of the Original Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises and mutual agreements set forth in the Original Agreement and this Amendment and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms used herein and not otherwise defined in this Amendment shall have the meanings ascribed to them in the Original Agreement.

Section 1.25 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"1.25 "Progeny" shall mean any mice that are produced or developed by or on behalf of Astellas in accordance with the terms of this Agreement by breeding or otherwise reproducing Mice delivered to it pursuant to Article III."

Section 1.27 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"1.27 "Regeneron Patent Rights" shall mean all Patent Rights owned or Controlled by Regeneron and/or its Affiliates during the term of this Agreement, which claim the Mice, Mice Materials or Mice Inventions or the use of the Mice, Mice Materials or Mice Inventions to make Antibodies in general, including, without limitation, the Patent Rights that are listed in Exhibit B. For the avoidance of doubt, Regeneron Patent Rights shall not include (i) any Patent Rights claiming methods relating to Antibody or Antibody Material generation that are not directly related to the Mice or Mice Materials and (ii) any Patent Rights claiming the use of Mice or Mice Materials to make Antibodies against any specific target. For the avoidance of doubt, Regeneron Patent Rights shall include any Patent Rights which Regeneron acquired from a Third Party to the extent included in this Agreement pursuant to Section 2.5, during the term of the Agreement."

2. Amendment to Section 3.4. The fifth sentence of Section 3.4 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"**********."

3. Amendment to Section 4.1. Section 4.1 of the Original Agreement is hereby deleted and void in its entirety and replaced with the following:

"'Company shall pay Regeneron one hundred sixty-five million United States dollars (US$165,000,000) on or before August 31, 2010 ("Up-Front Payment"). In addition, Company shall pay Regeneron one hundred thirty million United States dollars (US$130,000,000) on or before June 7, 2018, the eleventh anniversary of the Transfer Date (the "Second Payment"), unless this Agreement shall have been terminated prior to June 7, 2018 in accordance with Section 9.2. All payments to be made pursuant to this Section 4.1 shall be made by bank wire transfer in immediately available funds to an account designated by Regeneron."

For the avoidance of doubt, Company shall no longer be liable for the Adjusted Annual Fee which Company should pay on each of the fourth and fifth anniversaries of the Transfer Date under the Original Agreement.

4. Amendment to EXHIBIT B: Exhibit B of the Original Agreement is hereby deleted in its entirety and replaced with Exhibit B annexed to this Amendment.

5. Amendments to Section 5.2: The phrase of "as of the Effective Date" used in Section 5.2(g) and (k) in Section 5.2 of the Original Agreement is hereby deleted in its entirety and replaced with the phrase of "as of the Amendment Effective Date". The last sentence of Section 5.2 is hereby deleted in its entirety and replaced with the sentence "For purposes hereof, 'to its knowledge' shall mean actual knowledge as of the Amendment Effective Date with no duty of inquiry or investigation."

6. Amendment to Section 9.1. Section 9.1 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"Term. The term of this Agreement shall commence on the Effective Date and shall expire on June 7, 2023, the sixteenth anniversary of the Transfer Date, unless earlier terminated under the terms of this Agreement. For the avoidance of doubt, Company shall have the right to terminate this Agreement without cause upon written notice to Regeneron in accordance with Section 9.2(a). For the further avoidance of doubt, Company's obligation to pay royalties to Regeneron under Section 4.2 survives the expiration or termination of this Agreement in accordance with the terms of Article IV and Section 9.5."

7. Amendment to Section 9.2(a): Section 9.2(a) of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"Convenience. Company may elect to terminate this Agreement at any time by providing ninety (90) days' prior written notice to Regeneron. If such notice is sent with an effective date of termination prior to June 7, 2018, then Company shall not be required to make the Second Payment to Regeneron."

8. Amendment to Section 9.4: Section 9.4 of the Original Agreement is hereby amended as follows:

(i) The third sentence of Section 9.4(a) is hereby deleted and void in its entirety.

(ii) The following shall be added to the end of Section 9.4 as a new Section 9.4(e):

"(e) Upon termination of this Agreement by Company in accordance with Section 9.2(b) or 9.2(d), (i) Company shall not be required to make any further payments to Regeneron under Section 4.1, except that neither Party shall be relieved of any obligations arising prior to such termination, including any payment obligations which arose and are due with respect to any period prior to such termination and (ii) Regeneron shall return to Astellas part of the Up-Front Payment or Second Payment paid to Regeneron under Section 4.1 based on a pro-rata basis as calculated using the formula set forth below※. All payments to be made pursuant to this Section 9.4(e) shall be made by bank wire transfer in immediately available funds to an account designated by Astellas.

※In the event such termination occurs before the 11th anniversary of the Transfer Date:
=Up-Front Payment (US$165M) x (the number of years from the next anniversary of the Transfer Date following such termination until the 11th anniversary of the Transfer Date/7)

※In the event such termination occurs on and after the 11th anniversary date of the Transfer Date:
=Second Payment (US$130M) x (the number of years from the next anniversary of the Transfer Date following such termination until the 16th anniversary of the Transfer Date/5)"

9. Press Release. The Parties shall both issue a press release on the Amendment Effective Date with respect to the execution of this Amendment in the form annexed hereto as Exhibit A.

10. Term. This Amendment shall become effective on the Amendment Effective Date and be in force until the later to occur of the expiration or earlier termination of the Original Agreement.

11. Continuing Effect. Except as specifically modified in this Amendment, all of the terms of the Original Agreement shall remain in full force and effect.

12. Entire Agreement. The Original Agreement, as modified by, and together with, this Amendment, is the entire agreement between the Parties with respect to the subject matter of the Original Agreement, provided that, in the event of a conflict between the terms of the Original Agreement and the terms of this Amendment, the terms of this Amendment control.

13. Counterparts; Facsimile Signatures. This Amendment may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. Signatures provided by facsimile or other electronic transmission shall be deemed to be original signatures.

14. Governing Law; Submission to Jurisdiction. This Amendment shall be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York notwithstanding any provisions governing conflict of laws under such New York law to the contrary and without giving effect to the United States Convention on Contracts for the International Sale of Goods. Section 10.4 of the Original Agreement shall be deemed incorporated into and made a part of this Amendment.

IN WITNESS WHEREOF, the Parties have executed and delivered this Amendment in accordance with Section 10.8 of the Original Agreement as of the Amendment Effective Date.

ASTELLAS PHARMA INC.

By: /s/ Shinichi Tsukamoto
Name: Shinichi Tsukamoto
Title: Senior Corporate Executive,
Drug Discovery Research

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance &
Administration and Chief Financial Officer

EXHIBIT A

[LOGOS]

FOR IMMEDIATE RELEASE

Press Release

Astellas to Pay $295 Million to Extend License of Regeneron's *VelocImmune*® Antibody Technology through 2023

Tarrytown, NY and Tokyo, Japan – (July XX, 2010) –Regeneron Pharmaceuticals, Inc. ("Regeneron"; Nasdaq: **REGN)** and Astellas Pharma Inc. ("Astellas"; Headquarters: Tokyo, Japan; President & CEO: Masafumi Nogimori) announced today that Astellas has extended through 2023 the non-exclusive license agreement that allows Astellas to utilize Regeneron's *VelocImmune*® technology in its internal research programs to discover fully human monoclonal antibody product candidates.

Astellas will pay $165 million upfront and another $130 million in June 2018 unless it terminates the agreement prior to that date. Upon commercialization of any antibody products discovered utilizing *VelocImmune*, Astellas will pay a mid-single-digit royalty on product sales.

In March 2007, Astellas and Regeneron entered into a six-year *VelocImmune* license agreement pursuant to which Astellas made license payments of $20 million per year in 2007 through 2010. This amendment supersedes the original agreement and as such, Astellas will no longer make annual license payments in 2011 and 2012. Approximately 20 monoclonal antibody projects using *VelocImmune* technology are ongoing at Astellas and Agensys, Inc., a U.S. affiliate of Astellas.

"*VelocImmune* is the centerpiece of Regeneron's suite of technologies for the discovery and development of fully human monoclonal antibodies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories and Regeneron's Chief Scientific Officer. "We are pleased that Astellas, a company with a clear strategic commitment to developing therapeutic antibodies, has elected to continue to utilize the *VelocImmune* platform for its internal development programs."

"We are excited about this extension of the license agreement with Regeneron," said Shinichi Tsukamoto, Ph.D., Astellas' Senior Vice President, Drug Discovery Research. "As described in our recently announced mid-term management plan toward FY2014, Astellas is putting the highest strategic priority on the development of antibody drugs, and *VelocImmune* will continue to be the indispensable technology for our antibody drug development program."

VelocImmune

Regeneron's *VelocImmune* technology offers the potential to increase dramatically the speed and efficiency of discovering fully-human, therapeutic monoclonal antibodies. The *VelocImmune* platform generates fully human monoclonal antibodies (hMAbs) to address clinically relevant targets of therapeutic interest. The *VelocImmune* mouse, unlike other hMAb mice, mounts a robust immune response that is virtually indistinguishable from that of a wild type mouse, resulting in a reliable and efficient platform for discovering fully human monoclonal antibodies.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader by rapidly establishing a business model in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. Astellas has discovered a treatment for over-active bladder (OAB), Vesicare® (solifenacin succinate) and an immunosuppressant, Prograf® (tacrolimus), which have enabled Astellas to become an established leader in both Urology and Transplant. For more information on Astellas Pharma Inc., please visit Astellas' website at http://www.astellas.com/en.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Astellas, the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended March 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

###

Contact Information:
Astellas
Corporate Communications
Tel: +81-3-3244-3201 Fax: +81-3-5201-7473
http://www.astellas.com/en

Regeneron

Michael Aberman, M.D.
Investor Relations
914.345.7799
michael.aberman@regeneron.com

Peter Dworkin
Corporate Communications
914.345.7640
peter.dworkin@regeneron.com

EXHIBIT B

REGENERON PATENT RIGHTS

Patent No.:	6,586,251
USSN:	09/732,234
Inventors:	Economides, Murphy, Valenzuela, Yancopoulos
Title:	Methods of Modifying Eukaryotic Cells
Filing Date:	7 December 2000

Patent No.:	6,596,541
USSN:	09/784,859
PCT:	2003/6275
Inventors:	Murphy, Yancopoulos
Title:	Methods of Modifying Eukaryotic Cells
Filing Date:	16 February 2001 (continuation-in-part of 09/732,234)

Patent No.:	7,105,348
USSN:	10/076,840
Inventors:	Murphy, Yancopoulos
Title:	Methods of Modifying Eukaryotic Cells
Filing Date:	15 February 2002

780D AU	Patent No. 2002244023 Granted 23 August 2007
780D IN	Patent No. 234335 Granted 25 May 2009
780D JP	Patent No. 4412900 Granted 27 November 2009
780D NZ	Patent No. 527629 Granted 7 July 2005
780D SG	Patent No. 100103 Granted 30 November 2005
780D ZA	Patent No. 2003/6275 Granted 27 October 2004

****

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2010

/s/ LEONARD S. SCHLEIFER-
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2010

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
October 28, 2010

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
October 28, 2010

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 5/3/2011

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2011

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer ___

Non-accelerated filer ___ (Do not check if a smaller reporting company) Smaller reporting company ___

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes _____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of April 13, 2011:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,151,854
Common Stock, $0.001 par value	88,739,294

REGENERON PHARMACEUTICALS, INC.
Table of Contents
March 31, 2011

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at March 31, 2011 and December 31, 2010	3
	Condensed statements of operations (unaudited) for the three months ended March 31, 2011 and 2010	4
	Condensed statements of stockholders' equity (unaudited) for the three months ended March 31, 2011 and 2010	5
	Condensed statements of cash flows (unaudited) for the three months ended March 31, 2011 and 2010	6
	Notes to condensed financial statements (unaudited)	7-15
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	16-37
Item 3	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4	Controls and Procedures	37-38
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	38
Item 1A	Risk Factors	38-58
Item 6	Exhibits	58
SIGNATURE PAGE		59

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT MARCH 31, 2011 AND DECEMBER 31, 2010 (Unaudited)
(In thousands, except share data)

ASSETS	March 31, 2011	December 31, 2010
Current assets		
Cash and cash equivalents	$ 135,376	$ 112,572
Marketable securities	91,065	136,796
Accounts receivable from the sanofi-aventis Group	84,391	79,603
Accounts receivable - other	3,765	13,309
Prepaid expenses and other current assets	10,904	15,142
Total current assets	325,501	357,422
Restricted cash and marketable securities	7,520	7,518
Marketable securities	373,621	370,053
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	357,423	347,450
Other assets	10,228	6,789
Total assets	$ 1,074,293	$ 1,089,432
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 58,602	$ 53,658
Deferred revenue from sanofi-aventis, current portion	19,561	19,506
Deferred revenue - other, current portion	33,291	35,217
Facility lease obligations, current portion	798	675
Total current liabilities	112,252	109,056
Deferred revenue from sanofi-aventis	94,398	97,081
Deferred revenue - other	183,019	188,775
Facility lease obligations	159,353	159,353
Other long term liabilities	7,180	7,350
Total liabilities	556,202	561,617
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value, 40,000,000 shares authorized; shares issued and outstanding - 2,182,026 in 2011 and 2010	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 88,548,041 in 2011 and 87,238,301 in 2010	89	87
Additional paid-in capital	1,609,185	1,575,780
Accumulated deficit	(1,089,010)	(1,045,563)
Accumulated other comprehensive loss	(1,175)	(2,491)
Total stockholders' equity	518,091	527,815
Total liabilities and stockholders' equity	$ 1,074,293	$ 1,089,432

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended March 31,	
	2011	**2010**
Revenues		
Sanofi-aventis collaboration revenue	$ 85,329	$ 68,671
Other collaboration revenue	12,481	13,087
Technology licensing	7,845	10,038
Net product sales	4,427	9,853
Contract research and other	2,122	1,886
	112,204	103,534
Expenses		
Research and development	129,392	117,471
Selling, general, and administrative	23,411	14,223
Cost of goods sold	382	717
	153,185	132,411
Loss from operations	(40,981)	(28,877)
Other income (expense)		
Investment income	1,037	439
Interest expense	(3,719)	(2,084)
	(2,682)	(1,645)
Net loss before income tax benefit	(43,663)	(30,522)
Income tax benefit	(216)	
Net loss	$ (43,447)	$ (30,522)
Net loss per share, basic and diluted	$ (0.49)	$ (0.38)
Weighted average shares outstanding, basic and diluted	89,162	81,169

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the three months ended March 31, 2011 and 2010
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumul Other Comprehe
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (L
Balance, December 31, 2010	2,182	$ 2	87,218	$ 87	$ 1,575,788	$ (1,045,563)	$
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,218	2	15,102		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contributions			92		2,405		
Stock-based compensation charges					14,898		
Net loss						(43,447)	
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.2 million							
Balance, March 31, 2011	2,182	$ 2	88,528	$ 89	$ 1,609,185	$ (1,089,010)	$
Balance, December 31, 2009	2,345	$ 2	78,861	$ 79	$ 1,136,732	$ (341,095)	$
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			685	1	8,656		
Issuance of Common Stock in connection with Company 401(k) Savings Plan contributions			111		2,867		
Conversion of Class A Stock to Common Stock	(33)		33				
Stock-based compensation charges					8,834		
Net loss						(30,522)	
Change in net unrealized gain (loss) on marketable securities							
Balance, March 31, 2010	2,312	$ 2	79,690	$ 80	$ 1,157,089	$ (371,617)	$

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Three months ended March 31,	
	2011	**2010**
Cash flows from operating activities		
Net loss	$ (43,447)	$ (30,522)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	6,978	4,183
Non-cash compensation expense	14,901	8,934
Other non-cash charges and expenses	582	544
Changes in assets and liabilities		
Decrease (increase) in accounts receivable	4,956	(6,290)
Decrease (increase) in prepaid expenses and other assets	2,286	(2,483)
(Decrease) increase in deferred revenue	(10,310)	3,513
Increase in accounts payable, accrued expenses, and other liabilities	13,574	12,643
Total adjustments	32,867	20,944
Net cash used in operating activities	(10,580)	(9,578)
Cash flows from investing activities		
Purchases of marketable securities	(15,638)	(177,594)
Sales or maturities of marketable securities	58,151	63,936
Capital expenditures	(22,166)	(22,743)
Net cash provided by (used in) investing activities	20,347	(136,401)
Cash flows from financing activities		
Proceeds in connection with facility lease obligations		47,544
Payments in connection with facility lease obligations	(89)	(555)
Net proceeds from the issuance of Common Stock	13,343	9,226
Payments in connection with capital lease obligation	(217)	
Net cash provided by financing activities	13,037	56,215
Net increase (decrease) in cash and cash equivalents	22,804	(89,764)
Cash and cash equivalents at beginning of period	112,572	207,075
Cash and cash equivalents at end of period	$ 135,376	$ 117,311

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2010 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

Certain reclassifications have been made to the financial statements for the three months ended March 31, 2010 to conform with the current period's presentation.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 for the three months ended March 31, 2010.

ARCALYST® net product sales totaled $4.4 million and $9.9 million for the three months ended March 31, 2011 and 2010, respectively. ARCALYST® net product sales during the first three months of 2010 included $5.1 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at March 31, 2011 or 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.4 million and $0.7 million for the three months ended March 31, 2011 and 2010, respectively. ARCALYST® shipments to the Company's customers primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to 2008; therefore, the costs of these supplies were not included in costs of goods sold.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three months ended March 31, 2011 and 2010, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March 31,	
	2011	2010
Net loss (Numerator)	$ (43,447)	$ (30,522)
Weighted-average shares, in thousands (Denominator)	89,162	81,169
Basic and diluted net loss per share	$ (0.49)	$ (0.38)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the March 31, 2011 and 2010 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended March 31,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	22,378	21,400
Weighted average exercise price	$ 20.36	$ 18.59
Restricted Stock:		
Weighted average number, in thousands	845	501

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2011 and December 31, 2010 were $5.7 million and $10.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2010 and December 31, 2009 were $5.4 million and $9.8 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2010 and 2009 were $2.9 million and $2.6 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in facility lease obligations and property, plant, and equipment at March 31, 2010 was $0.8 million of capitalized and deferred interest for the quarter ended March 31, 2010, as the related facilities being leased by the Company were under construction and lease payments on these facilities did not commence until January 2011.

Included in other assets at March 31, 2011 and December 31, 2010 was $1.9 million and $0.2 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at March 31, 2011 and December 31, 2010 were $2.0 million and $1.4 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at March 31, 2011 and December 31, 2010 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $4.6 million and $3.6 million at March 31, 2011 and December 31, 2010, respectively, and the aggregate cost basis of which was $4.0 million at both March 31, 2011 and December 31, 2010. The Company also held restricted marketable securities at both March 31, 2011 and December 31, 2010, which consisted of debt securities, as detailed below, that collateralize (i) a letter of credit in connection with the Company's lease of facilities in Tarrytown, New York and (ii) capital lease obligations.

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at March 31, 2011 and December 31, 2010. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair	Unrealized		
At March 31, 2011	**Cost Basis**	**Value**	**Gains**	**(Losses)**	**Net**
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 38,551	$ 38,593	$ 42		$ 42
U.S. government guaranteed corporate bonds	39,670	39,939	269		269
U.S. government guaranteed collateralized mortgage obligations	1,588	1,590	2		2
Municipal bonds	10,786	10,799	13		13
Mortgage-backed securities	146	144		$ (2)	(2)
	90,741	91,065	326	(2)	324
Maturities between one and five years					
U.S. government obligations	348,753	346,784	10	(1,979)	(1,969)
U.S. government guaranteed corporate bonds	15,546	15,503		(43)	(43)
Municipal bonds	6,546	6,552	6		6
	370,845	368,839	16	(2,022)	(2,006)
Maturities between five and six years					
Mortgage-backed securities	281	144		(137)	(137)
	461,867	460,048	342	(2,161)	(1,819)
Restricted					
Maturities within one year					
U.S. government obligations	2,924	2,926	2		2
Maturities between one and three years					
U.S. government obligations	4,138	4,115		(23)	(23)
	7,062	7,041	2	(23)	(21)
	$ 468,929	$ 467,089	$ 344	$ (2,184)	$ (1,840)
At December 31, 2010					
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 83,635	$ 83,684	$ 54	$ (5)	$ 49
U.S. government guaranteed corporate bonds	48,173	48,531	358		358
U.S. government guaranteed collateralized mortgage obligations	2,027	2,131	104		104
Municipal bonds	1,597	1,603	6		6
Mortgage-backed securities	875	847		(28)	(28)
	136,307	136,796	522	(33)	489

At December 31, 2010 (continued)	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Maturities between one and five years					
U.S. government obligations	352,345	350,683	64	(1,726)	(1,662)
U.S. government guaranteed corporate bonds	15,522	15,477		(45)	(45)
Mortgage-backed securities	110	38		(72)	(72)
	367,977	366,198	64	(1,843)	(1,779)
Maturities between five and seven years					
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year					
U.S. government obligations	2,922	2,921		(1)	(1)
Maturities between one and three years					
U.S. government obligations	4,135	4,118		(17)	(17)
	7,057	7,039		(18)	(18)
	$ 511,625	$510,276	$ 586	$ (1,935)	$ (1,349)

At March 31, 2011 and December 31, 2010, marketable securities included an additional unrealized gain of $0.6 million and an unrealized loss of $0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at March 31, 2011 and December 31, 2010. The debt securities listed at March 31, 2011, excluding mortgage-backed securities, mature at various dates through December 2013. The mortgage-backed securities listed at March 31, 2011 mature at various dates through February 2017.

	Less than 12 Months		12 Months or Greater		Total	
At March 31, 2011	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Unrestricted						
U.S. government obligations	$ 331,731	$ (1,979)			$ 331,731	$ (1,979)
U.S. government guaranteed corporate bonds	15,501	(43)			15,501	(43)
Mortgage-backed securities			$ 288	$ (139)	288	(139)
	347,234	(2,022)	288	(139)	347,522	(2,161)
Restricted						
U.S. government obligations	4,115	(23)			4,115	(23)
	4,115	(23)			4,115	(23)
	$ 351,349	$ (2,045)	$ 288	$ (139)	$ 351,637	$ (2,184)

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2010	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 340,444	$ (1,731)			$ 340,444	$ (1,731)
U.S. government guaranteed corporate bonds	19,905	(45)			19,905	(45)
Equity securities	3,612	(433)			3,612	(433)
Mortgage-backed securities			$ 1,128	$ (141)	1,128	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Restricted						
U.S. government obligations	6,154	(18)			6,154	(18)
	6,154	(18)			6,154	(18)
	$ 369,215	$ (2,227)	$ 1,128	$ (141)	$ 370,343	$ (2,368)

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2011 and 2010, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at March 31, 2011 and December 31, 2010, were as follows:

		Fair Value Measurements at Reporting Date Using		
At March 31, 2011	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 385,377		$ 385,377	
U.S. government guaranteed corporate bonds	55,442		55,442	
U.S. government guaranteed collateralized mortgage obligations	1,590		1,590	
Municipal bonds	17,351		17,351	
Mortgage-backed securities	288		288	
Equity securities	4,638	$ 4,638		
	464,686	4,638	460,048	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,041		7,041	
	$ 471,727	$ 4,638	$ 467,089	

		Fair Value Measurements at Reporting Date Using		
At December 31, 2010	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 434,367		$ 434,367	
U.S. government guaranteed corporate bonds	64,008		64,008	
U.S. government guaranteed collateralized mortgage obligations	2,131		2,131	
Municipal bonds	1,603		1,603	
Mortgage-backed securities	1,128		1,128	
Equity securities	3,612	$ 3,612		
	506,849	3,612	503,237	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,039		7,039	
	$ 513,888	$ 3,612	$ 510,276	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the three months ended March 31, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover a portion of the security's $1.1 million carrying value. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three months ended March 31, 2011.

The Company holds one Level 3 marketable security, which had no fair value at March 31, 2011 and December 31, 2010. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the security's lack of liquidity. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three months ended March 31, 2011 and 2010. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2011 and 2010.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Inventory

Inventories as of March 31, 2011 and December 31, 2010 consist of the following:

	March 31, 2011	December 31, 2010
Raw materials	$ 162	$ 592
Work in process	3,634	699
Finished goods	85	132
	$ 3,881	$ 1,423

At March 31, 2011, $0.1 million of inventories were included in prepaid expenses and other current assets and $3.8 million of inventories were included in other assets. At December 31, 2010, inventories were included in prepaid expenses and other current assets.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2011 and December 31, 2010 consist of the following:

	March 31, 2011	December 31, 2010
Accounts payable	$ 16,146	$ 15,593
Accrued payroll and related costs	20,039	12,025
Accrued clinical trial expense	8,606	9,727
Accrued property, plant, and equipment costs	3,940	7,622
Other accrued expenses and liabilities	7,112	6,441
Payable to Bayer HealthCare	2,759	2,254
	$ 58,602	$ 53,658

8. Income Taxes

For the three months ended March 31, 2011 and 2010, the Company incurred net losses for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three months ended March 31, 2011, the Company recognized a $0.2 million income tax benefit in connection with the net tax effect of the decrease in the Company's unrealized loss on "available-for-sale" marketable securities, which is included in other comprehensive loss. For the three months ended March 31, 2010, no provision or benefit for income taxes was recorded.

9. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current ordinary course legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

As previously reported, on November 19, 2010, the Company filed a complaint against Genentech, Inc. in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon the Company's submission to the FDA of a Biologics License Application ("BLA") for VEGF Trap-Eye for the treatment of wet AMD, the Company filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, the Company and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, the Company voluntarily dismissed its original complaint in favor of proceeding with its second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that the Company is entitled to the declaratory relief being sought by it, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. The Company believes Genentech's counterclaims are without merit and intends to defend against them vigorously. As this matter is at a very early stage, at this time the Company is not able to predict the probability of the outcome or an estimate of loss, if any, related to this matter.

The Company has initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S.

10. Recently Issued Accounting Standards

Multiple-deliverable revenue arrangements

During the first quarter of 2011 the Company adopted amended authoritative guidance issued by the Financial Accounting Standards Board ("FASB") on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-deliverable revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. The Company is applying this amended guidance prospectively for new or materially modified arrangements, of which there were none during the three months ended March 31, 2011. The adoption of this guidance did not have a material impact on the Company's financial statements.

Milestone method of revenue recognition

During the first quarter of 2011, the Company adopted amended authoritative guidance issued by FASB codifying the milestone method of revenue recognition as an acceptable revenue recognition model when a milestone is deemed to be substantive. The Company has historically accounted for milestones under the milestone method; as such the adoption of this guidance did not have a material impact on the Company's financial statements.

In accordance with the Company's accounting policy for recognition of revenue in connection with collaboration agreements, as previously disclosed in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company earns substantive performance milestone payments in connection with its collaboration agreements to develop and commercialize product candidates with the sanofi-aventis Group and Bayer HealthCare LLC. Descriptions of these collaboration agreements, including various financial terms and conditions, were provided in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Under the Company's collaboration agreement with sanofi-aventis to jointly develop and commercialize ZALTRAP™ (aflibercept), the Company may receive up to $400 million in substantive milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight ZALTRAP™ oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five ZALTRAP™ oncology indications in Japan. Under the Company's global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies, for each drug candidate identified under the collaboration's Discovery and Preclinical Development Agreement, sanofi-aventis has the option to license rights to the candidate under the collaboration's License and Collaboration Agreement and co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, sanofi-aventis must make a $10.0 million substantive milestone payment to the Company. Under the Company's license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the U.S., the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"), the Company is eligible to receive up to $50 million in future substantive milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the U.S..

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among other things, the nature, timing, and possible success and therapeutic applications of our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare LLC, to be canceled or terminated without any product success, and risks associated with third-party intellectual property and pending or future litigation relating thereto. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have 11 product candidates in clinical development, including three that are in late-stage (Phase 3) studies. All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye (aflibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of serious eye diseases; ZALTRAP™ (aflibercept), also known as VEGF Trap, which is being developed in oncology in collaboration with sanofi-aventis; and ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofi-aventis:

- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and eosinophilic asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*®. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® – CAPS

Net product sales of ARCALYST® (rilonacept) in the first quarter of 2011 were $4.4 million. In the same quarter of 2010, net product sales of ARCALYST® were $9.9 million, which included $5.1 million of ARCALYST® net product sales made in the first quarter of 2010 and $4.8 million of previously deferred net product sales, as described below under "Results of Operations."

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST® is available for prescription in the U.S. for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye (aflibercept ophthalmic solution) is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared VEGF Trap-Eye and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-angiogenic agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (following three initial monthly doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with VEGF Trap-Eye who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis®. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month.

A generally favorable safety profile was observed for both VEGF Trap-Eye and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in February 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe and other countries.

VEGF Trap-Eye is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment as measured by the ETDRS eye chart. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

We and Bayer HealthCare announced in December 2010 that in the COPERNICUS study, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In the study, VEGF Trap-Eye was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%), consisting of individual reports of corneal abrasion, endophalmitis, retinal vein occlusion, and reduced visual acuity, and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with VEGF Trap-Eye and two (2.7%) in the 73 patients treated with sham injections.

In April 2011, we and Bayer HealthCare announced that in the GALILEO study, VEGF Trap-Eye also met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In this trial, 60.2% of patients receiving 2.0 mg of VEGF Trap-Eye monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). Patients receiving 2.0 mg of VEGF Trap-Eye monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

Based on these positive results, we intend to submit a regulatory application for marketing approval for VEGF Trap-Eye in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in this indication in Europe in 2012.

In April 2011, we and Bayer Healthcare announced that Bayer Healthcare initiated a Phase 3 study outside the U.S. to evaluate the safety and efficacy of VEGF Trap-Eye in DME. The study, named VIVID-DME (VEGF Trap-Eye In Vision Inpairment Due to DME), has three study arms. In the first arm, patients will be treated every month with 2.0 mg of VEGF Trap-Eye. In the second arm, patients will be treated with 2.0 mg of VEGF Trap-Eye every two months after an initial phase of monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint of the study is mean change in visual acuity from baseline as measured by the ETDRS eye chart. All patients will be followed for three years. We intend to commence a second Phase 3 study in DME, the VISTA-DME study (VEGF Trap-Eye: Investigation of Safety, Treatment effect, and Anatomic outcomes in DME), in the U.S., Canada, and other countries, later in 2011.

In January 2011, Regeneron and Bayer HealthCare initiated a Phase 3 trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the U.S. of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan. Bayer HealthCare will market VEGF Trap-Eye outside the U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Commencing on the first commercial sale of VEGF Trap-Eye in a major market country outside the U.S., we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. Within the U.S., we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We have received $60 million in development milestone payments and can earn up to $50 million in future milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the U.S. We can also earn up to $135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the U.S. achieve certain specified levels starting at $200 million.

2. ZALTRAP™ (also known as aflibercept or VEGF Trap) – Oncology

ZALTRAP™ (aflibercept) is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

ZALTRAP™ is being developed globally in cancer indications in collaboration with sanofi-aventis. In April 2011, we and sanofi-aventis announced that the Phase 3 VELOUR trial evaluating ZALTRAP™ in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in the second-line treatment of metastatic colorectal cancer (mCRC). Full results will be presented at an upcoming medical meeting. The most frequent adverse events reported with ZALTRAP™ in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection, hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Based upon these positive findings, we and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the European Medicines Agency (EMA) in the second half of 2011.

In March 2011, we and sanofi-aventis announced results from the Phase 3 VITAL trial evaluating ZALTRAP™ for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding ZALTRAP™ to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of ZALTRAP™ to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the ZALTRAP™ arm compared to 8.9% in the placebo arm. Consistent with published literature reporting on combined cytotoxic and anti-VEGF therapy, the incidence of adverse events was higher in the ZALTRAP™ arm compared to placebo. The most frequent Grade 3/4 adverse events included fatigue, stomatitis, disease progression, and hypertension.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP™ as a first-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. The VENICE trial is being monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the trial and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in this trial. Based on projected event rates, an interim analysis of the VENICE trial is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) of ZALTRAP™ in first-line mCRC in combination with FOLFOX [folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin] is fully enrolled. Initial data from this study are anticipated in the second half of 2011.

ZALTRAP™ Collaboration with sanofi-aventis

We and sanofi-aventis globally collaborate on the development and commercialization of ZALTRAP™. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of ZALTRAP™ outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of ZALTRAP™, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight ZALTRAP™ oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the ZALTRAP™ collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis out of our share of ZALTRAP™ profits for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAP™ profits in the quarter unless we elect to reimburse sanofi-aventis at a faster rate.

3. ARCALYST®– Inflammatory Diseases

ARCALYST® (rilonacept) is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We have been conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program consists of three studies: PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations).

In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients initiating uric acid-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$).

All secondary endpoints of the study were highly positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.8% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, $p<0.001$). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, $p<0.001$).

A total of 241 patients were randomized in PRE-SURGE 1. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

In February 2011, we reported the results of PRE-SURGE 2 and RE-SURGE. In the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, which was identical to PRE-SURGE 1 in design and analysis, 248 patients were randomized. ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). Among secondary endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 82% (6.0% with ARCALYST® 160 mg, 8.5% with ARCALYST® 80 mg, and 32.9% with placebo, $p\leq0.001$). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 63% (20.5% with ARCALYST® 160 mg, 25.6% with ARCALYST® 80 mg, and 56.1% with placebo, $p\leq0.001$).

ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most frequently reported adverse event was upper respiratory tract infection (15.5% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 12.2% with placebo). Overall, the cumulative rate of infections was 27.4% in patients treated with ARCALYST® 160 mg, 28.0% in patients treated with ARCALYST® 80 mg, and 25.6% in patients treated with placebo. Injection site reactions were more commonly reported in patients treated with ARCALYST® (17.9% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 1.2% with placebo). These results were consistent with those in PRE-SURGE 1.

We also announced that in the RE-SURGE study, which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. RE-SURGE evaluated 1,315 patients who were at risk for gout flares while initiating or continuing uric acid-lowering drug treatment. Other than injection site reactions, the incidence of treatment-emergent adverse events was generally well-balanced among the 985 patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg and the 330 patients who received placebo. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST® (15.2%) than with placebo (3.3%). Overall, the cumulative rate of infections was 20.1% in patients treated with ARCALYST® and 19.1% in placebo patients. Serious infections were reported in 0.5% of patients treated with ARCALYST® and 0.9% of placebo patients. Deaths were reported for 0.3% of patients treated with ARCALYST® and 0.9% of placebo patients.

In the RE-SURGE study, ARCALYST® met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Based on the results of the three Phase 3 studies, we plan to submit in mid-2011 a supplemental BLA for U.S. regulatory approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We own worldwide rights to ARCALYST®.

4. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune*® technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported.

In early 2011, we initiated Phase 2 studies of REGN727 in patients with hypercholesterolemia in combination with statin therapy. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (IL-6R Antibody) for inflammatory diseases

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, Actemra® (tocilizumab), a registered trademark of Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune*® technology that has completed Phase 1 studies, the results of which were presented at the annual meetings of the European League Against Rheumatism (EULAR) in June 2010 and the American College of Rheumatology in October 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in mid-2011. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune®* technology that is designed to bind to IL-4R. A Phase 1 trial of REGN668 in healthy volunteers has been completed. A Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma are underway. REGN668 is being developed in collaboration with sanofi-aventis.

7. REGN421 (Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune®* technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a Phase 1 study in an oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is a fully human monoclonal antibody generated using our *VelocImmune®* technology, which is being developed for cancer indications in collaboration with sanofi-aventis.

9. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune®* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF.

In May 2010, we announced positive results from an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with sanofi-aventis.

10. REGN728 and REGN846

In the fourth quarter of 2010, clinical trials began with two additional fully human monoclonal antibodies generated using our *VelocImmune*® technology that are part of the sanofi-aventis collaboration, REGN728 and REGN846. The targets of these antibodies have not been disclosed.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as ZALTRAP™ and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®*. The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune®* and our entire *VelociSuite™* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune®* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse®* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of $85.0 million from sanofi-aventis. Pursuant to the collaboration, sanofi-aventis is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified through discovery research under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with sanofi-aventis generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the U.S. The parties will share profits outside the U.S. on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the U.S. at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the U.S. exceed $1.0 billion on a rolling 12-month basis.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

Under the amended discovery agreement, sanofi-aventis agreed to fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi-aventis has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, sanofi-aventis is also obligated to fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, sanofi-aventis funded $137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement.

From the collaboration's inception in November 2007 through March 31, 2011, sanofi-aventis has funded a total of $354.8 million of our costs under the discovery agreement and a total of $294.1 million of our development costs under the license agreement, or a total of $648.9 million in funding for our antibody research and development activities during this period.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Under this agreement, sanofi-aventis is required to pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune®* technology.

AstraZeneca UK Limited. In February 2007, we entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million annual, non-refundable payment to us in each of the first quarters of 2007, 2008, 2009, and 2010. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. We remain entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by MedImmune using our *VelocImmune®* technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. While our royalties under this agreement could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received $22.6 million from the grant's inception through March 31, 2011 and are entitled to receive an additional $2.7 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General:

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2011, we had a cumulative loss of $1.1 billion, principally related to our research and development activities. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. We submitted a BLA to the FDA in February 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe and other countries. We plan to submit a BLA to the FDA in the second half of 2011 for marketing approval of VEGF Trap-Eye in CRVO in the U.S., and Bayer HealthCare is planning to submit regulatory applications for marketing approval of VEGF Trap-Eye in CRVO in Europe in 2012. We also plan to submit a supplemental BLA to the FDA in mid-2011 for marketing approval in the U.S. of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the EMA in the second half of 2011. We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product (s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and development efforts, the progress of our efforts to commercialize our late-stage product candidates, the timing of certain expenses, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when our late-stage product candidates, including VEGF Trap-Eye in wet AMD, will receive regulatory approval or, if such approval is received, whether we will be able to successfully commercialize such product(s), or if we do commercialize such product(s), whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2011 to date were, and plans for the next 12 months are, as follows:

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
VEGF Trap–Eye	• Submitted a BLA to the U.S. FDA for the treatment of wet AMD • FDA accepted BLA for wet AMD and granted our request for Priority Review • Reported positive six-month results in the Phase 3 GALILEO trial in CRVO • Bayer Healthcare initiated a Phase 3 trial in DME outside the U.S. • Initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia	• Target date for FDA decision on VEGF Trap-Eye BLA is August 20, 2011 • Report two-year data from VIEW 1 and VIEW 2 in wet AMD, and one-year data from COPERNICUS and GALILEO in CRVO in the second half of 2011 • Submit a BLA to the FDA for the treatment of CRVO in the second half of 2011 • Initiate a second DME Phase 3 trial in the U.S. in the second half of 2011

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
ZALTRAP™	• Reported positive results in the Phase 3 VELOUR trial in mCRC • Reported results for the VITAL trial in NSCLC	• Submit a BLA to the FDA for the treatment of mCRC in the second half of 2011 • IDMC review of interim results for the Phase 3 VENICE trial in prostate cancer in mid-2011 • Report initial results in the Phase 2 AFFIRM trial in colorectal cancer in the second half of 2011
ARCALYST®	• Reported positive results from two Phase 3 studies for the prevention of gout flares (PRE-SURGE 2 and RESURGE)	• Submit a supplemental BLA to the FDA for the prevention of gout flares in mid-2011
REGN727 (PCSK9 Antibody)	• Initiated Phase 2 studies for LDL cholesterol reduction	• Report initial data from the Phase 2 program for LDL cholesterol reduction
REGN88 (IL-6R Antibody)	• Continued patient enrollment in studies in rheumatoid arthritis and ankylosing spondylitis	• Report initial Phase 2 data in rheumatoid arthritis and ankylosing spondylitis
REGN668 (IL-4R Antibody)	• Initiated Phase 1b study in atopic dermatitis and Phase 2 proof of concept study in eosinophilic asthma	• Initiate Phase 2 program in atopic dermatitis
REGN421 (Dll4 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate a Phase 1b program in advanced malignancies
REGN910 (ANG2 Antibody)	• Continued patient enrollment in Phase 1 program	
REGN475 (NGF Antibody)	• On clinical hold	
REGN728 (target not disclosed)	• Continued patient enrollment in Phase 1 program	
REGN846 (target not disclosed)	• Continued patient enrollment in Phase 1 program	

Results of Operations

Three Months Ended March 31, 2011 and 2010

Net Loss

Regeneron reported a net loss of $43.4 million, or $0.49 per share (basic and diluted), for the first quarter of 2011, compared to a net loss of $30.5 million, or $0.38 per share (basic and diluted) for the first quarter of 2010. The increase in our net loss in 2011 was principally due to higher research and development expenses and higher selling, general, and administrative expenses, partly offset by higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended March 31, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi-aventis	$ 85.3	$ 68.7
Bayer HealthCare	12.5	13.1
Total collaboration revenue	97.8	81.8
Technology licensing revenue	7.9	10.0
Net product sales	4.4	9.9
Contract research and other revenue	2.1	1.8
Total revenue	$ 112.2	$ 103.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earned from sanofi-aventis, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP™ collaboration and $85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue	Three months ended March 31,	
(In millions)	2011	2010
ZALTRAP™		
Regeneron expense reimbursement	$ 7.2	$ 4.9
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total ZALTRAP™	9.7	7.4
Antibody		
Regeneron expense reimbursement	73.2	59.3
Recognition of deferred revenue related to up-front and other payments	2.0	1.6
Recognition of revenue related to *VelociGene®* agreement	0.4	0.4
Total antibody	75.6	61.3
Total sanofi-aventis collaboration revenue	$ 85.3	$ 68.7

Sanofi-aventis' reimbursement of our ZALTRAP™ expenses increased in the first quarter of 2011 compared to same period in 2010, primarily due to higher costs related to manufacturing ZALTRAP™ clinical supplies. As of March 31, 2011, $30.1 million of the original $105.0 million of up-front payments related to ZALTRAP™ was deferred and will be recognized as revenue in future periods.

In the first quarter of 2011, sanofi-aventis' reimbursement of our antibody expenses consisted of $42.1 million under the discovery agreement and $31.1 million of development costs under the license agreement, compared to $26.7 million and $32.6 million, respectively, in the first quarter of 2010. The higher reimbursement amount under the discovery agreement in the first quarter of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities.

Recognition of deferred revenue related to sanofi-aventis' $85.0 million up-front payment and other payments increased in the first quarter of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to these payments for such funding from sanofi-aventis is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment. As of March 31, 2011, $23.9 million of such funding from sanofi-aventis was received or receivable, compared to $5.1 million as of March 31, 2010; as a result, we recognized more deferred revenue in the first quarter of 2011 than in the same quarter of 2010. As of March 31, 2011, $78.3 million of the sanofi-aventis payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. In both the three months ended March 31, 2011 and 2010, we recognized $0.4 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Three months ended March 31,**	
(In millions)	**2011**	**2010**
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 10.0	$ 10.6
Recognition of deferred revenue related to up-front and other milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 12.5	$ 13.1

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased slightly in the first quarter of 2011 compared to the same period in 2010. In the first quarter of 2011, we incurred lower clinical development costs in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 DA VINCI trial in DME, partly offset by higher internal costs in connection with regulatory filings in wet AMD. In connection with the recognition of deferred revenue related to the $75.0 million up-front payment and $20.0 million milestone payment received in August 2007, as of March 31, 2011, $44.5 million of these payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and is being recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and will be recognized as revenue ratably over a seven-year period beginning in mid-2011. In connection with our *VelocImmune®* license agreement with AstraZeneca, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the final year of the agreement. In the first quarter of 2011 and 2010, we recognized $7.9 million and $10.0 million, respectively, of technology licensing revenue related to these agreements. As of March 31, 2011, $168.7 million of technology licensing payments received from Astellas was deferred and will be recognized as revenue in future periods.

Net Product Sales

For the three months ended March 31, 2011 and 2010, we recognized as revenue $4.4 million and $9.9 million, respectively, of ARCALYST® net product sales. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. At March 31, 2011 and 2010, there was no deferred revenue related to ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended March 31, 2011 and 2010 included $1.0 million and $1.1 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $153.2 million in the first quarter of 2011 from $132.4 million in the first quarter of 2010. Our average headcount in the first quarter of 2011 increased to 1,432 from 1,087 in the same period of 2010 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first quarter of 2011 and 2010 included a total of $14.8 million and $8.8 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended March 31, 2011		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 121.6	$ 7.8	$ 129.4
Selling, general, and administrative	16.4	7.0	23.4
Cost of goods sold	0.4		0.4
Total operating expenses	$ 138.4	$ 14.8	$ 153.2

	For the three months ended March 31, 2010		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 112.5	$ 5.0	$ 117.5
Selling, general, and administrative	10.4	3.8	14.2
Cost of goods sold	0.7		0.7
Total operating expenses	$ 123.6	$ 8.8	$ 132.4

The increase in total Non-cash Compensation Expense in the first quarter of 2011 was primarily attributable to (i) the recognition of higher expense in the first quarter of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to $129.4 million in the first quarter of 2011 from $117.5 million in the same period of 2010. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2011 and 2010:

Research and Development Expenses	**For the three months ended March 31,**		**Increase**
(In millions)	**2011**	**2010**	**(Decrease)**
Payroll and benefits (1)	$ 42.6	$ 27.7	$ 14.9
Clinical trial expenses	19.0	32.2	(13.2)
Clinical manufacturing costs (2)	22.2	20.0	2.2
Research and other development costs	15.3	12.8	2.5
Occupancy and other operating costs	14.0	12.0	2.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	16.3	12.8	3.5
Total research and development expenses	$ 129.4	$ 117.5	$ 11.9

(1) Includes $6.9 million and $4.3 million of Non-cash Compensation Expense for the three months ended March 31, 2011 and 2010, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $0.9 million and $0.7 million of Non-cash Compensation Expense for the three months ended March 31, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, our Phase 3 VIEW 1 trial of VEGF Trap-Eye in wet AMD and our Phase 2 DA VINCI trial in DME, and our clinical development program for NGF, which is currently on clinical hold. Clinical manufacturing costs increased due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility and higher costs related to manufacturing ZALTRAP™ clinical supplies, partly offset by lower costs related to manufacturing ARCALYST® clinical supplies. Research and other development costs increased primarily due to higher costs associated with filing our BLA for VEGF Trap-Eye in wet AMD. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the first quarter of 2011.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the three months ended March 31,		Increase
(In millions)	2011	2010	(Decrease)
ARCALYST®	$ 8.9	$ 20.1	$ (11.2)
VEGF Trap-Eye	39.6	33.6	6.0
ZALTRAP™	6.4	3.9	2.5
REGN88	6.7	4.9	1.8
REGN727	7.1	5.2	1.9
Other antibody candidates in clinical development	12.6	18.9	(6.3)
Other research programs & unallocated costs	48.1	30.8	17.3
Total research and development expenses	$ 129.4	$ 117.5	$ 11.9

Drug development and approval in the U.S. is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, ZALTRAP™, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors" under "Risks Related to the Development and Approval of Our Product Candidates," "Risks Related to Commercialization of Products," and "Regulatory and Litigation Risks." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $23.4 million in the first quarter of 2011 from $14.2 million in the same period of 2010 due primarily to increases in compensation expense principally in connection with higher headcount in the first quarter of 2011, higher market research costs primarily in connection with VEGF Trap-Eye, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons described above.

Cost of Goods Sold

Cost of goods sold in the first quarter of 2011 and 2010 was $0.4 million and $0.7 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $1.0 million in the first quarter of 2011 from $0.4 million in the same period of 2010, due primarily to higher yields on, and higher average balances of, cash and marketable securities.

Interest expense increased to $3.7 million in the first quarter of 2011 from $2.1 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Three months ended March 31, 2011 and 2010

At March 31, 2011, we had $607.6 million in cash, cash equivalents, and marketable securities (including $7.5 million of restricted cash and marketable securities) compared with $626.9 million at December 31, 2010 (including $7.5 million of restricted cash and marketable securities). In January 2011, we received, from Bayer HealthCare, a $10.0 million milestone payment, which was earned in 2010, in connection with the COPERNICUS study of VEGF Trap-Eye in CRVO.

Cash Used in Operating Activities

Net cash used in operating activities was $10.6 million in the first quarter of 2011 and $9.6 million in the first quarter of 2010. Our net losses of $43.4 million in the first quarter of 2011 and $30.5 million in the first quarter of 2010 included $14.8 million and $8.8 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $7.0 million and $4.2 million in the first quarter of 2011 and 2010, respectively.

At March 31, 2011, accounts receivable decreased by $5.0 million, compared to end-of-year 2010, primarily due to the receipt of the $10.0 million milestone payment in January 2011 from Bayer HealthCare, as discussed above. Our deferred revenue at March 31, 2011 decreased by $10.3 million, compared to end-of-year 2010, primarily due to the amortization of previously received and deferred $20.0 million payments under our license agreements with AstraZeneca and Astellas. Accounts payable, accrued expenses, and other liabilities increased by $13.6 million at March 31, 2011, compared to end-of-year 2010, primarily in connection with higher liabilities for payroll-related expenses.

At March 31, 2010, accounts receivable increased by $6.3 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. At March 31, 2010, accounts payable, accrued expenses, and other liabilities increased by $12.6 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses and payroll and related costs.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $20.3 million in the first quarter of 2011, compared with net cash used in investing activities of $136.4 million in the first quarter of 2010. In the first quarter of 2011, sales or maturities of marketable securities exceeded purchases by $42.5 million, whereas in the first quarter of 2010, purchases of marketable securities exceeded sales or maturities by $113.7 million. Capital expenditures in the first quarter of 2011 and 2010 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease.

Cash Provided by Financing Activities

Net cash provided by financing activities was $13.0 million in the first quarter of 2011 and $56.2 million in the first quarter of 2010. In the first quarter of 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $13.3 million in the first quarter of 2011 and $9.2 million in the first quarter of 2010.

Fair Value of Marketable Securities

At March 31, 2011 and December 31 2010, we held marketable securities whose aggregate fair value totaled $471.7 million and $513.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2011		December 31, 2010	
Investment type	**Fair Value**	**Percent**	**Fair Value**	**Percent**
Unrestricted				
U.S. government agency securities	$ 385.4	82%	$ 434.4	85%
U.S. government-guaranteed corporate bonds	55.4	12%	64.0	13%
Municipal bonds	17.4	4%		
Equity securities	4.6	1%	3.6	1%
U.S. government guaranteed collateralized mortgage obligations	1.6		2.1	
Other			1.6	
Mortgage-backed securities	0.3		1.1	
Total unrestricted marketable securities	464.7	99%	506.8	99%
Restricted				
U.S. government agency securities	7.0	1%	7.1	1%
Total marketable securities	$ 471.7	100%	$ 513.9	100%

In addition, at March 31, 2011 and December 31, 2010, we had $135.9 million and $113.0 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled $22.2 million and $22.7 million for the first three months of 2011 and 2010, respectively. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, sanofi-aventis has funded $0.5 million and $4.6 million, respectively, of agreed-upon capital expenditures incurred by us during the first quarters of 2011 and 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at March 31, 2011 and 2010.

We expect to incur capital expenditures of approximately $50 to $65 million during the remainder of 2011 primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our ZALTRAP™ and antibodies collaborations are, generally, fully funded by sanofi-aventis. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our VEGF Trap-Eye collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 30-40% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and VEGF Trap-Eye). For 2011, we also currently estimate that approximately 15-25% of our funding requirements will be directed toward the planned commercialization of our late-stage product candidates; approximately 20-30% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, whether or not our late-stage product candidates receive regulatory approval, the market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credits totaling $3.8 million, including the $3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2011, we had $0.7 million of financing available under a capital equipment lease line. Aside from this lease line, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $5.5 million and $1.6 million decrease in the fair value of our investment portfolio at March 31, 2011 and 2010, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at March 31, 2011 compared to the same period of 2010.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in the first quarter of 2010. During the first quarter of 2011, we did not recognize any other-than-temporary impairment charges.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current ordinary course legal proceedings to have a material adverse effect on our business or financial condition.

As previously reported, on November 19, 2010, we filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon our submission to the FDA of a BLA for VEGF Trap-Eye for the treatment of wet AMD, we filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, we and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, we voluntarily dismissed our original complaint in favor of proceeding with our second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12 (b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. We believe Genentech's counterclaims are without merit and intend to defend against them vigorously.

We have initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2011, we had a cumulative loss of $1.1 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of those product(s). We believe our existing capital resources, together with funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase, which could result in our capital being consumed significantly before that time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our late-stage product candidates, expenses related to clinical trials testing ARCALYST® or VEGF Trap-Eye, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs, and even if regulatory approval is obtained for such product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of March 31, 2011, our cash, cash equivalents, and marketable securities totaled $607.6 million (including $7.5 million of restricted cash and marketable securities) and represented 57% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $464.7 million at March 31, 2011, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in 2010. The current economic environment and the volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to the Development and Approval of Our Product Candidates

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of VEGF Trap-Eye for the treatment of wet AMD and other ophthalmologic diseases, which has not yet been approved by the FDA or by regulatory authorities in countries outside the U.S. If there are material delays in obtaining marketing approval for VEGF Trap-Eye, or such approval is not obtained, our business, results of operations, and financial condition will be materially harmed.

The FDA has substantial discretion in deciding whether or not VEGF Trap-Eye should be granted approval in the U.S. based on the benefits and risks of VEGF Trap-Eye in treating the particular ophthalmologic diseases in which it is being studied in clinical trials. Analogous regulatory authorities in countries outside the U.S. have similar discretion as to approval of VEGF Trap-Eye in those countries. In February 2011, we submitted a BLA for VEGF Trap-Eye for the treatment of wet AMD to the FDA. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the BLA is August 20, 2011. However, the FDA is not under any legal obligation to complete its review of the BLA or to render a decision within this timeframe, and it is not unusual for the FDA's review of and/or rendering a decision with respect to a BLA that has been granted Priority Review to extend beyond the initial target date. For instance, the FDA may request additional clinical or other data or information, including by issuing a complete response letter which may require that we submit additional clinical or other data or impose other conditions that must be met in order to secure final approval of our BLA. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The granting of Priority Review designation for our BLA does not change the standards for approval and does not ensure that VEGF Trap-Eye for the treatment of wet AMD will be approved.

Whether VEGF Trap-Eye is approved by the FDA for the treatment of wet AMD, and the timing thereof, will depend on many factors, including the following:

- whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of VEGF Trap-Eye demonstrates that it is safe and effective as a treatment for wet AMD;
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for VEGF Trap-Eye are adequate, that the labeling is satisfactory and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient; and
- the timing and nature of the FDA's comments and questions, or those of any advisers to the FDA if the FDA seeks external advice, regarding our BLA for VEGF Trap-Eye for the treatment of wet AMD, the time required to respond to any such comments and questions and to obtain final labeling, and any other delays that may be associated with the BLA review process.

If we experience material delays in obtaining marketing approval for VEGF Trap-Eye for wet AMD in the U.S., we will not receive product revenues during the delay, which would negatively affect our business, results of operations, and financial condition. Such delays may also increase the challenge of competitive products as doctors and patients continue to use existing therapies. If we do not obtain approval to market VEGF Trap-Eye for wet AMD in the U.S., or if there are material delays in obtaining such approval, our business and financial position will be materially harmed.

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them, which would materially and negatively impact our business and prospects.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, VEGF Trap-Eye for the treatment of ophthalmologic diseases, and/or ZALTRAP™ for one or more oncology indications, the value of our company and our results of operations will be materially harmed. As with our BLA for VEGF Trap-Eye for the treatment of wet AMD, we cannot predict as to whether or when our other product candidates, including ZALTRAP™ for second-line treatment of mCRC, VEGF Trap-Eye for CRVO and DME, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, will receive regulatory approval. If we are unable to obtain such approval(s), or if we are materially delayed in doing so, our business and prospects would be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the U.S., we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for FDA approval of ARCALYST®, and the EMA approval of rilonacept, for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the U.S. or any other country. We may never receive regulatory approval for any of our current or future product candidates.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs and could substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP, requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, and following approval in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the U.S., we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the U.S., we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, regulatory approval for our product candidates may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GCPs. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, financial condition, and results of operations may be materially harmed.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are testing ZALTRAP™ and VEGF Trap-Eye in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials.

In April 2011 we announced that our Phase 3 VELOUR trial of ZALTRAP™ met its primary endpoint of improving overall survival in the second-line treatment of mCRC, and that based upon these positive results, we and sanofi-aventis plan to submit regulatory applications for marketing approval to the FDA and EMA in the second half of 2011. However, we can give no assurance as to whether or when such applications, if submitted, will be approved. ZALTRAP™ is also in a Phase 3 clinical trial in combination with a standard chemotherapy regimen for the treatment of first-line androgen independent prostate cancer. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that ZALTRAP™ will be safe or effective in this cancer setting. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (Bevacizumab Injection), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of ZALTRAP™ in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD, the treatment of CRVO, and the treatment of DME. As described above, in February 2011, we submitted a BLA to the FDA for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Although we reported positive Phase 3 trial results with VEGF Trap-Eye in wet AMD after one year of treatment, the Phase 3 trials will continue for an additional year and there is a risk that the results from the second year of the studies could differ from the previously reported results; such difference could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval. We also reported positive Phase 3 trial results with VEGF Trap-Eye in CRVO after six months of treatment. The trials are continuing and there is a risk that the one-year results from the studies could differ from the previously reported results, and such final results could delay or preclude regulatory approval. We also reported positive results of a Phase 2 trial in the treatment of DME and that we have initiated a Phase 3 program in that indication. A number of other potential new drugs and biologics which showed promising results in Phase 1 and 2 clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals, and this could occur with respect to subsequent clinical trials of VEGF Trap-Eye for the treatment of DME.

Based on the results of three Phase 3 studies, we plan to submit a supplemental BLA to the FDA seeking approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. However, there can be no assurance as to if or when the FDA will grant such approval.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP™ as a first-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

ZALTRAP™ is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAP™ and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like VEGF Trap-Eye, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development of ZALTRAP™ for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

As more patients begin to use ARCALYST® if it receives approval for the prevention of gout flares in patients initiating uric acid-lowering therapy, and to the extent it is tested in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Ilaris® (canakinumab), a registered trademark of Novartis, Kineret® (anakinra), a registered trademark of Biovitmm AB, Enbrel® (etanercept), a registered trademark of Amgen, Inc. and Pfizer Inc., and Remicade® (infliximab) a registered trademark of Centocor Ortho Biotech, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test ZALTRAP™ and VEGF Trap-Eye with more sensitive assays in different patient populations, we will find that subjects given ZALTRAP™ and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to continue to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the U.S. may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third-party patents or other proprietary rights, and the costs and expenses of ongoing patent litigation have been and will likely continue to be significant.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune®* technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAP™ or VEGF Trap-Eye infringes any valid claim in these patents or patent applications. As described above under Item 1 ("Legal Proceedings"), in November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York, seeking a declaratory judgment that no activities relating to the Regeneron VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. In April 2011, we and Genentech entered into a Joint Stipulation whereby Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the case for lack of subject matter jurisdiction. On April 25, 2011, Genentech filed an answer to our complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. We believe Genentech's counterclaims are without merit and intend to defend against them vigorously. However, it is possible that there could be an adverse determination or judgment in this litigation that would materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of ZALTRAP™ or VEGF Trap-Eye, or resulting in a damage award. In addition, irrespective of the outcome of this litigation, we have incurred and will likely continue to incur significant costs and expenses associated with this matter, which has negatively affected, and will likely continue to negatively affect, our results of operations. We have initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S., which could have similar or other adverse outcomes that would materially harm our business and which, irrespective of the outcomes, may also entail significant costs and expenses.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, ZALTRAP™, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the U.S.

Further, we are aware of a number of other third-party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Risks Related to Manufacturing and Supply

We have limited manufacturing capacity, and we rely on contract manufacturers for fill and finish, which could result in our being unable to successfully commercialize our products if they receive regulatory approval and to continue to develop our clinical candidates.

Our manufacturing facility is likely to be inadequate to produce sufficient commercial quantities of all of our late-stage products if they receive regulatory approval. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. We rely entirely on third-party manufacturers for filling and finishing services. Generally, in order for third parties to perform any step in the manufacturing and supply chain, we must transfer technology to the third party which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these third parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to manufacture and supply sufficient commercial quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators or third-party manufacturers or other vendors in our supply chain which adversely affect the timely manufacture and supply of our products, our business, financial condition, and results of operations may be materially harmed.

We also must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we will need to expand our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our product candidates if they are approved for marketing. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. The FDA and analogous foreign regulatory authorities must determine that our manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for VEGF-Trap-Eye, ZALTRAP™, or our other late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize VEGF Trap-Eye, ZALTRAP™, and our other late-stage product candidates if they receive regulatory approval and could also delay our clinical development programs. As a result, our business, financial condition, and results of operations may be materially harmed.

We may also be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

Our ability to manufacture our products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe third-party patents.

Our ability to manufacture ARCALYST®, and our late-stage product candidates, including VEGF Trap-Eye and ZALTRAP™ in our Rensselaer, New York facilities, or to utilize third-party contract manufacturers to produce our products or perform fill/finish services, depends on our and their ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products which could materially harm our business, operations and prospects.

If any of our clinical programs are delayed or discontinued, we may face costs related to the unused capacity at our manufacturing facilities and those of our third-party contract manufacturers performing fill/finish services.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, or their clinical development is delayed, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing fill/finish services for us.

Third-party supply or other failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for the manufacture and formulation of ARCALYST® and of our product candidates, including VEGF Trap-Eye and ZALTRAP™, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of ARCALYST® and our product candidates. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials or commercial supply, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

Even if we receive regulatory approval to market our products, we may be unsuccessful in commercializing them, which would materially harm our business, results of operations, and financial condition.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture and commercialize those products. Even if we obtain regulatory approval for our product candidates, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, results of operations, and financial condition would be severely harmed.

If we are unable to establish sales, marketing, and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell our products.

We are selling ARCALYST® for the treatment of CAPS ourselves in the U.S., primarily through third-party service providers. We have no sales or distribution personnel in the U.S. and have only a small staff with commercial capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates receive regulatory approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all.

We currently have no sales, marketing, commercial, or distribution capabilities outside the U.S. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of ZALTRAP™ in cancer indications, should it be approved in the future by regulatory authorities for marketing. Under the terms of our license and collaboration agreement with Bayer HealthCare, we will rely on Bayer HealthCare for sales, marketing, and distribution of VEGF Trap-Eye in countries outside the U.S. should it be approved for marketing in such countries.

We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the U.S. and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if such products receive regulatory approval. Though we are currently actively pursuing establishing our own sales, marketing, and distribution organization in anticipation of receiving regulatory approval to market and sell in the U.S. VEGF Trap-Eye for the treatment of wet AMD, and in anticipation of filing for and receiving regulatory approval to market and sell in the U.S. VEGF Trap-Eye for the treatment of CRVO and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment, we may be unsuccessful in doing so.

We have no experience in sales, marketing, or distribution of products in substantial commercial quantities or in establishing and managing the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network, and we may be unable to establish such infrastructure on a timely basis. In building a sales force in anticipation of the possible approval and launch in the U.S. of VEGF Trap-Eye in wet AMD and other ophthalmologic indications for which it is currently in Phase 3 clinical trials and of ARCALYST® for the prevention of gout flares, we may be unable to successfully recruit and retain within the required time frame an adequate number of qualified sales representatives and may encounter difficulties in retaining third parties to provide sales, marketing, or distribution resources. Even if we hire the qualified sales and marketing personnel, and establish the required infrastructure we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell in the U.S. VEGF Trap-Eye, ARCALYST® for the prevention of gout flares, or any of our other product candidates, if they receive regulatory approval. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining the sales force and distribution capabilities may be disproportional, particularly in the near term, compared to the revenues we may be able to generate on sales in the U.S. of VEGF Trap-Eye or ARCALYST® for the prevention of gout flares. We cannot guarantee that we will be successful in commercializing VEGF Trap-Eye, ARCALYST® for the prevention of gout flares, or any of our other product candidates.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain given their method of administration, and because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than ZALTRAP™ and may offer competitive advantages over our molecule. Each of Pfizer, Onyx Pharmaceuticals, Inc. (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin®, and their extensive, ongoing clinical development plan for Avastin® in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support ZALTRAP™ and to obtain regulatory approval of ZALTRAP™ in these cancer settings. This may delay or impair our ability to successfully develop and commercialize ZALTRAP™. In addition, even if ZALTRAP™ is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® for the treatment of wet AMD, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following RVO. Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as siRNAs that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin®.

The NEI and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT), were reported in April 2011 and indicated that Avastin® dosed monthly was non-inferior to Lucentis® dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Even if our BLA for VEGF Trap-Eye for the treatment of wet AMD which was filed in February 2011 is approved, it may be difficult for VEGF Trap-Eye in this or other eye indications for which it may be approved to compete against Lucentis®, because doctors and patients have had significant experience using this medicine. Moreover, the recently reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which VEGF Trap-Eye will face in this or other eye indications for which it may be approved. In addition, while we believe that ZALTRAP™ would not be well tolerated if administered directly to the eye, if ZALTRAP™ is approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage ZALTRAP™ for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to VEGF Trap-Eye if it is ever approved for wet AMD or other eye indications.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel®, Remicade®, Humira® (adalimumab), a registered trademark of Abbott Laboratories, Simponi® (golimumab), a registered trademark of Centocor, the IL-1 receptor antagonist Kineret®, Ilaris®, and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients have had significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma Ltd. (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. Canakinumab is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, canakinumab is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and plan to submit a BLA for U.S. regulatory approval in mid-2011. In January 2011, Novartis announced that the results of two Phase 3 studies with canakinumab focused on reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout were positive. Novartis has also reported that regulatory filings for the use of canakinumab in gouty arthritis have been completed in the European Union in 2010 and in the U.S. in the first quarter of 2011, based on the results of these two Phase 3 studies. Canakinumab is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other Nonsteroidal anti-inflammatory drugs (NSAIDS), are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs will make it difficult for us to successfully commercialize ARCALYST® in these diseases.

Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune®* technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor, and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our operations or future prospects.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products, and we may be unable to profitably commercialize ARCALYST® for CAPS.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDS. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if U.S. and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the U.S. for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third-party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers, our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material negative effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Regulatory and Litigation Risks

If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third-party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of product(s). Because we produce multiple product candidates at our facility in Rensselaer, New York, including ARCALYST®, VEGF Trap-Eye, and ZALTRAP™, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates. Any delay, interruption or other issues that arise in the manufacture, fill/finish, packaging, or storage of any drug products or product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business and prospects. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product, which could be seriously detrimental to our business and financial condition.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved product, ARCALYST® for the treatment of CAPS, that they have been injured by a side effect associated with the drug. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of our third-party fill/finish or other providers. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell approved products in the future, in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the federal Patient Protection and Affordable Care Act, or PPACA, pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the Public Company Accounting Oversight Board (PCAOB), the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation (so-called "say on pay") and proxy access. On January 25, 2011, the SEC adopted final rules concerning "say on pay". Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2010, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;

- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The PPACA potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN727, REGN88, REGN668, REGN421, REGN910, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the U.S. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for ZALTRAP™ is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize ZALTRAP™ in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of ZALTRAP™. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the ZALTRAP™ program. If the ZALTRAP™ program continues, we will rely on sanofi-aventis to assist with funding the ZALTRAP™ program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the U.S., and lead the commercialization of ZALTRAP™. While we cannot assure you that ZALTRAP™ will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize ZALTRAP™ in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of ZALTRAP™ and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for ZALTRAP™ would create substantial new and additional risks to the successful development and commercialization of ZALTRAP™.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to continue to develop VEGF Trap-Eye and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. As the VEGF Trap-Eye program continues, we will continue to rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the U.S., obtain regulatory approval outside the U.S., and provide all sales, marketing, and commercial support for the product outside the U.S. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the U.S. using its sales force. While we cannot assure you that VEGF Trap-Eye will ever receive regulatory approval in or outside the U.S. or be successfully commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the U.S. will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the U.S. and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the U.S. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and sales of ARCALYST® for CAPS.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, Good Laboratory Practices (GLPs), or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for our, product candidates.

We rely on third-party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our sales of ARCALYST® for the treatment of CAPS will suffer and ARCALYST® for that indication may never become profitable.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers and other key members of our senior management team. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we prepare for commercialization in the U.S. of our late-stage product candidates should they receive regulatory approval, we will also be highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- announcement of actions by the FDA or foreign regulatory authorities regarding our currently pending or future application(s) for regulatory approval of our late-stage product candidate(s);
- announcement of submission of an application for regulatory approval of one or more of our late-stage product candidates;
- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third-party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 13, 2011, our five largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 55.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 13, 2011. In September 2003, sanofi-aventis (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 sanofi-aventis purchased an additional 12 million newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with sanofi-aventis, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, sanofi-aventis purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of April 13, 2011, sanofi-aventis beneficially owned 15,816,953 shares of our Common Stock, representing approximately 17.8% of the shares of Common Stock then outstanding. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2011, holders of Class A Stock held 19.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 13, 2011:

- our current executive officers and directors beneficially owned 12.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2011, and 25.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2011; and
- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 55.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 13, 2011. In addition, these six shareholders held 59.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 13, 2011.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our ZALTRAP™ collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
31.1	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	- Interactive Data File
101.INS	- XBRL Instance Document
101.SCH	- XBRL Taxonomy Extension Schema
101.CAL	- XBRL Taxonomy Extension Calculation Linkbase
101.LAB	- XBRL Taxonomy Extension Label Linkbase
101.PRE	- XBRL Taxonomy Extension Presentation Linkbase
101.DEF	- XBRL Taxonomy Extension Definition Document

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: May 3, 2011

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 3, 2011

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 3, 2011

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
May 3, 2011

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
May 3, 2011

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 7/28/2011

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2011

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer ___

Non-accelerated filer ___ (Do not check if a smaller reporting company) Smaller reporting company ___

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes _____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of July 15, 2011:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,126,717
Common Stock, $0.001 par value	89,499,900

REGENERON PHARMACEUTICALS, INC.
Table of Contents
June 30, 2011

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at June 30, 2011 and December 31, 2010	3
	Condensed statements of operations (unaudited) for the three and six months ended June 30, 2011 and 2010	4
	Condensed statements of stockholders' equity (unaudited) for the six months ended June 30, 2011 and 2010	5
	Condensed statements of cash flows (unaudited) for the six months ended June 30, 2011 and 2010	6
	Notes to condensed financial statements (unaudited)	7-16
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	17-43
Item 3	Quantitative and Qualitative Disclosures About Market Risk	43
Item 4	Controls and Procedures	43
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	44
Item 1A	Risk Factors	44-66
Item 6	Exhibits	66
SIGNATURE PAGE		67

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT JUNE 30, 2011 AND DECEMBER 31, 2010 (Unaudited)
(In thousands, except share data)

ASSETS	June 30, 2011	December 31, 2010
Current assets		
Cash and cash equivalents	$ 254,312	$ 112,572
Marketable securities	55,271	136,796
Accounts receivable from Sanofi	81,643	79,603
Accounts receivable - other	2,921	13,509
Prepaid expenses and other current assets	19,026	15,142
Total current assets	413,273	357,622
Restricted cash and marketable securities	8,165	7,518
Marketable securities	251,256	370,053
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	361,883	347,450
Other assets	12,287	6,789
Total assets	$ 1,046,864	$ 1,089,432
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 81,665	$ 53,658
Deferred revenue from Sanofi, current portion	19,720	19,506
Deferred revenue - other, current portion	33,606	35,217
Facility lease obligations, current portion	877	675
Total current liabilities	135,868	109,056
Deferred revenue from Sanofi	91,712	97,081
Deferred revenue - other	174,987	188,775
Facility lease obligations	159,457	159,353
Other long term liabilities	6,806	7,350
Total liabilities	568,830	561,617
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,126,717 in 2011 and 2,182,056 in 2010	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 89,416,015 in 2011 and 87,238,301 in 2010	89	87
Additional paid-in capital	1,630,362	1,575,780
Accumulated deficit	(1,151,515)	(1,045,563)
Accumulated other comprehensive loss	(904)	(2,491)
Total stockholders' equity	478,034	527,815
Total liabilities and stockholders' equity	$ 1,046,864	$ 1,089,432

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2011	**2010**	**2011**	**2010**
Revenues				
Sanofi collaboration revenue	$ 84,446	$ 84,941	$ 169,775	$ 153,612
Other collaboration revenue	11,123	13,633	23,604	26,722
Technology licensing	5,228	10,037	13,073	20,075
Net product sales	5,039	5,197	9,466	15,049
Contract research and other	1,974	2,076	4,096	3,962
	107,810	115,886	220,014	219,420
Expenses				
Research and development	143,149	124,526	272,541	241,997
Selling, general, and administrative	24,585	14,679	47,996	28,902
Cost of goods sold	395	405	777	1,122
	168,129	139,610	321,314	272,021
Loss from operations	(60,319)	(23,724)	(101,300)	(52,601)
Other income (expense)				
Investment income	998	592	2,035	1,031
Interest expense	(4,047)	(2,342)	(7,766)	(4,426)
	(3,049)	(1,750)	(5,731)	(3,395)
Net loss before income tax benefit	(63,368)	(25,474)	(107,031)	(55,996)
Income tax benefit	(863)		(1,079)	
Net loss	$ (62,505)	$ (25,474)	$ (105,952)	$ (55,996)
Net loss per share, basic and diluted	$ (0.69)	$ (0.31)	$ (1.18)	$ (0.69)
Weighted average shares outstanding, basic and diluted	90,436	81,492	89,759	81,330

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the six months ended June 30, 2011 and 2010
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2010	2,187	$ 2	87,238	$ 87	$ 1,575,780	$ (1,045,985)	$ (2,491)	$ 527,813	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			2,026	2	23,792			23,794	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			92		3,405			3,405	
Issuance of restricted Common Stock under Long-Term Incentive Plan			5						
Conversion of Class A Stock to Common Stock	(85)		85						
Stock-based compensation charges					27,385			27,385	
Net loss						(105,932)		(105,932)	$ (105,932)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $1.1 million							1,587	1,587	1,587
Balance, June 30, 2011	2,127	$ 2	89,446	$ 89	$ 1,630,362	$ (1,151,917)	$ (904)	$ 478,034	$ (104,345)
Balance, December 31, 2009	2,245	$ 2	78,861	$ 79	$ 1,336,732	$ (941,095)	$ 1,944	$ 396,762	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			878	1	11,391			11,392	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			114		2,867			2,867	
Issuance of restricted Common Stock under Long-Term Incentive Plan			10						
Conversion of Class A Stock to Common Stock	(63)		63						
Stock-based compensation charges					17,541			17,541	
Net loss						(54,996)		(54,996)	$ (54,996)
Change in net unrealized gain (loss) on marketable securities							(1,350)	(1,350)	(1,350)
Balance, June 30, 2010	2,182	$ 2	79,923	$ 80	$ 1,368,531	$ (996,091)	$ (906)	$ 371,216	$ (57,346)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Six months ended June 30,	
	2011	**2010**
Cash flows from operating activities		
Net loss	$ (105,952)	$ (55,996)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	14,880	8,707
Non-cash compensation expense	27,197	17,541
Other non-cash charges and expenses, net	832	1,623
Changes in assets and liabilities		
Decrease (increase) in accounts receivable	8,548	(29,628)
(Increase) decrease in prepaid expenses and other assets	(8,158)	1,601
(Decrease) increase in deferred revenue	(20,554)	16,616
Increase in accounts payable, accrued expenses, and other liabilities	39,577	18,105
Total adjustments	61,322	34,568
Net cash used in operating activities	(44,630)	(21,428)
Cash flows from investing activities		
Purchases of marketable securities	(15,638)	(222,168)
Sales or maturities of marketable securities	216,631	136,711
Capital expenditures	(37,030)	(45,324)
Increase in restricted cash	(681)	(1,800)
Net cash provided by (used in) investing activities	163,282	(132,581)
Cash flows from financing activities		
Proceeds in connection with facility lease obligations		47,544
Payments in connection with facility lease obligations	(227)	(674)
Net proceeds from the issuance of Common Stock	23,752	12,064
Payments in connection with capital lease obligation	(437)	
Net cash provided by financing activities	23,088	58,934
Net increase (decrease) in cash and cash equivalents	141,740	(95,075)
Cash and cash equivalents at beginning of period	112,572	207,075
Cash and cash equivalents at end of period	$ 254,312	$ 112,000

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2010 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

Certain reclassifications have been made to the financial statements for the six months ended June 30, 2010 to conform with the current period's presentation.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 for the six months ended June 30, 2010.

ARCALYST® net product sales totaled $5.0 million and $5.2 million for the three months ended June 30, 2011 and 2010, respectively, and $9.5 million and $15.0 million for the six months ended June 30, 2011 and 2010, respectively. ARCALYST® net product sales during the first six months of 2010 included $10.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at June 30, 2011 or 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.4 million for both the three months ended June 30, 2011 and 2010, and $0.8 million and $1.1 million for the six months ended June 30, 2011 and 2010, respectively. ARCALYST® shipments to the Company's customers primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to 2008; therefore, the costs of these supplies were not included in costs of goods sold.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2011 and 2010, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended June 30,	
	2011	2010
Net loss (Numerator)	$ (62,505)	$ (25,474)
Weighted-average shares, in thousands (Denominator)	90,436	81,492
Basic and diluted net loss per share	$ (0.69)	$ (0.31)

	Six Months Ended June 30,	
	2011	2010
Net loss (Numerator)	$ (103,952)	$ (55,996)
Weighted-average shares, in thousands (Denominator)	89,799	81,330
Basic and diluted net loss per share	$ (1.16)	$ (0.69)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the June 30, 2011 and 2010 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	20,967	21,288
Weighted average exercise price	$ 20.71	$ 18.67
Restricted Stock:		
Weighted average number, in thousands	846	510

	Six months ended June 30,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	21,668	21,344
Weighted average exercise price	$ 20.48	$ 18.63
Restricted Stock:		
Weighted average number, in thousands	846	506

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2011 and December 31, 2010 were $3.4 million and $10.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2010 and December 31, 2009 were $4.1 million and $9.8 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2010 and 2009 were $2.9 million and $2.6 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in facility lease obligations and property, plant, and equipment at June 30, 2010 was $1.7 million of capitalized and deferred interest for the six months ended June 30, 2010, as the related facilities being leased by the Company were under construction and lease payments on these facilities did not commence until January 2011.

The Company incurred capital lease obligations of $0.7 million during the six months ended June 30, 2011 in connection with acquisitions of equipment.

Included in marketable securities at June 30, 2011 and December 31, 2010 were $0.8 million and $1.4 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at June 30, 2011 and December 31, 2010 consisted of debt securities, as detailed below, and equity securities. The aggregate fair value of the equity securities was $4.3 million and $3.6 million at June 30, 2011 and December 31, 2010, respectively, and the aggregate cost basis was $4.0 million at both June 30, 2011 and December 31, 2010. The Company also held restricted marketable securities at both June 30, 2011 and December 31, 2010, which consisted of debt securities, as detailed below, that collateralize letters of credit and lease obligations.

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at June 30, 2011 and December 31, 2010. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

At June 30, 2011	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 9,142	$ 9,159	$ 17		$ 17
U.S. government guaranteed corporate bonds	31,936	32,088	152		152
U.S. government guaranteed collateralized mortgage obligations	1,321	1,322	1		1
Municipal bonds	12,712	12,730	19	$ (1)	18
Mortgage-backed securities	73	72		(1)	(1)
	55,184	55,371	189	(2)	187
Maturities between one and five years					
U.S. government obligations	227,542	228,070	551	(23)	528
U.S. government guaranteed corporate bonds	15,393	15,408	15		15
Municipal bonds	3,310	3,323	13		13
Mortgage-backed securities	275	135		(140)	(140)
	246,520	246,936	579	(163)	416
	301,704	302,307	768	(165)	603
Restricted					
Maturities within one year					
U.S. government obligations	2,688	2,889	1		1
Maturities between one and three years					
U.S. government obligations	5,176	5,182	8	(2)	6
	8,064	8,071	9	(2)	7
	$ 309,768	$ 310,378	$ 777	$ (167)	$ 610

At December 31, 2010					
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 83,635	$ 83,684	$ 54	$ (5)	$ 49
U.S. government guaranteed corporate bonds	48,173	48,531	358		358
U.S. government guaranteed collateralized mortgage obligations	2,027	2,131	104		104
Municipal bonds	1,597	1,603	6		6
Mortgage-backed securities	875	847		(28)	(28)
	136,307	136,796	522	(33)	489
Maturities between one and five years					
U.S. government obligations	352,345	350,683	64	(1,726)	(1,662)
U.S. government guaranteed corporate bonds	15,522	15,477		(45)	(45)
Mortgage-backed securities	110	38		(72)	(72)
	367,977	366,198	64	(1,843)	(1,779)
Maturities between five and seven years					
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year					
U.S. government obligations	2,922	2,921		(1)	(1)
Maturities between one and three years					
U.S. government obligations	4,135	4,118		(17)	(17)
	7,057	7,039		(18)	(18)
	$ 511,625	$ 510,276	$ 586	$ (1,935)	$ (1,349)

At June 30, 2011 and December 31, 2010, marketable securities included an additional unrealized gain of $0.3 million and an unrealized loss of $0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at June 30, 2011 and December 31, 2010. The debt securities held at June 30, 2011, excluding mortgage-backed securities, mature at various dates through December 2013. The mortgage-backed securities held at June 30, 2011 have various estimated maturity dates through July 2015.

	Less than 12 Months		12 Months or Greater		Total	
At June 30, 2011	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 25,649	$ (23)			$ 25,649	$ (23)
Municipal bonds	3,264	(1)			3,264	(1)
Mortgage-backed securities			$ 207	$ (141)	207	(141)
	28,913	(24)	207	(141)	29,120	(165)
Restricted						
U.S. government obligations	1,431	(2)			1,431	(2)
	1,431	(2)			1,431	(2)
	$ 30,344	$ (26)	$ 207	$ (141)	$ 30,551	$ (167)

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2010	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 340,444	$ (1,731)			$ 340,444	$ (1,731)
U.S. government guaranteed corporate bonds	19,005	(45)			19,005	(45)
Equity securities	3,612	(433)			3,612	(433)
Mortgage-backed securities			$ 1,128	$ (141)	1,128	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Restricted						
U.S. government obligations	6,154	(18)			6,154	(18)
	6,154	(18)			6,154	(18)
	$ 369,215	$ (2,227)	$ 1,128	$ (141)	$ 370,343	$ (2,368)

Realized gains and losses are included as a component of investment income. For the three and six months ended June 30, 2011 and 2010, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at June 30, 2011 and December 31, 2010, were as follows:

		Fair Value Measurements at Reporting Date Using		
At June 30, 2011	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 237,229		$ 237,229	
U.S. government guaranteed corporate bonds	47,496		47,496	
U.S. government guaranteed collateralized mortgage obligations	1,322		1,322	
Municipal bonds	16,053		16,053	
Mortgage-backed securities	207		207	
Equity securities	4,320	$ 4,320		
	306,627	4,320	302,307	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	8,071		8,071	
	$ 314,698	$ 4,320	$ 310,378	

		Fair Value Measurements at Reporting Date Using		
At December 31, 2010	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 434,367		$ 434,367	
U.S. government guaranteed corporate bonds	64,008		64,008	
U.S. government guaranteed collateralized mortgage obligations	2,131		2,131	
Municipal bonds	1,603		1,603	
Mortgage-backed securities	1,128		1,128	
Equity securities	3,612	$ 3,612		
	506,849	3,612	503,237	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,039		7,039	
	$ 513,888	$ 3,612	$ 510,276	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the six months ended June 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover a portion of the security's carrying value. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three and six months ended June 30, 2011, and the three months ended June 30, 2010, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

The Company holds one Level 3 marketable security, which had no fair value at June 30, 2011 and December 31, 2010. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the security's lack of liquidity. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and six months ended June 30, 2011 and 2010. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and six months ended June 30, 2011 and 2010.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Inventory

Inventories as of June 30, 2011 and December 31, 2010 consist of the following:

	June 30, 2011	December 31, 2010
Raw materials	$ 223	$ 592
Work in process	6,188	699
Finished goods	131	132
	$ 6,542	$ 1,423

At June 30, 2011, $0.6 million of inventories were included in prepaid expenses and other current assets and $5.9 million of inventories were included in other assets. At December 31, 2010, inventories were included in prepaid expenses and other current assets.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2011 and December 31, 2010 consist of the following:

	June 30, 2011	December 31, 2010
Accounts payable	$ 25,935	$ 15,589
Accrued payroll and related costs	26,029	12,025
Accrued clinical trial expense	9,802	9,727
Accrued property, plant, and equipment costs	1,057	7,622
Other accrued expenses and liabilities	7,810	6,441
Payable to Bayer HealthCare LLC	11,012	2,254
	$ 81,665	$ 53,658

8. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and six months ended June 30, 2011 and 2010, the components of comprehensive loss are:

	Three months ended June 30,	
	2011	2010
Net loss	$ (62,505)	$ (25,474)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.9 million in 2011	1,271	(1,023)
Total comprehensive loss	$ (61,234)	$ (26,497)

	Six months ended June 30,	
	2011	2010
Net loss	$ (105,952)	$ (55,996)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $1.1 million in 2011	1,587	(1,350)
Total comprehensive loss	$ (104,365)	$ (57,346)

9. Income Taxes

For the three and six months ended June 30, 2011 and 2010, the Company incurred net losses for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three and six months ended June 30, 2011, the Company recognized an income tax benefit of $0.9 million and $1.1 million, respectively, in connection with the net tax effect of the decrease in the Company's unrealized loss on "available-for-sale" marketable securities, which is included in other comprehensive loss. For the three and six months ended June 30, 2010, no provision or benefit for income taxes was recorded.

10. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current ordinary course legal proceedings to have a material adverse effect on the Company's business or financial condition. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

As previously reported, on November 19, 2010, the Company filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to the Company's VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon the Company's submission to the FDA of a BLA for EYLEA™ (also known as VEGF Trap-Eye) for the treatment of wet AMD, the Company filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, the Company and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, the Company voluntarily dismissed its original complaint in favor of proceeding with its second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that the Company is entitled to the declaratory relief being sought by the Company, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that the Company is entitled to the declaratory relief being sought by the Company, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, the Company replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of the Company's prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. The Company believes Genentech's counterclaims are without merit and intends to continue to defend against them vigorously. As this litigation is at an early stage, at this time the Company is not able to predict the probability of the outcome or an estimate of loss, if any, related to this matter.

The Company has initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S.

11. Recently Issued Accounting Standards

Multiple-deliverable revenue arrangements

During the first quarter of 2011 the Company adopted amended authoritative guidance issued by the Financial Accounting Standards Board ("FASB") on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-deliverable revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. The Company is applying this amended guidance prospectively for new or materially modified arrangements, of which there were none during the six months ended June 30, 2011. The adoption of this guidance did not have a material impact on the Company's financial statements.

Milestone method of revenue recognition

During the first quarter of 2011, the Company adopted amended authoritative guidance issued by the FASB codifying the milestone method of revenue recognition as an acceptable revenue recognition model when a milestone is deemed to be substantive. Since the Company has historically accounted for milestones under the milestone method, the adoption of this guidance did not have a material impact on the Company's financial statements.

In accordance with the Company's accounting policy for recognition of revenue in connection with collaboration agreements, as previously disclosed in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company earns substantive performance milestone payments in connection with its collaboration agreements to develop and commercialize product candidates with Sanofi and Bayer HealthCare. Descriptions of these collaboration agreements, including various financial terms and conditions, were provided in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Under the Company's collaboration agreement with Sanofi to jointly develop and commercialize ZALTRAP™ (aflibercept, also known as VEGF Trap), the Company may receive up to $400 million in substantive milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight ZALTRAP™ oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five ZALTRAP™ oncology indications in Japan. Under the Company's global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies, for each drug candidate identified under the collaboration's Discovery and Preclinical Development Agreement, Sanofi has the option to license rights to the candidate under the collaboration's License and Collaboration Agreement and co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10 million substantive milestone payment to the Company. Under the Company's license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the U.S., EYLEA™, the Company is eligible to receive up to $50 million in future substantive milestone payments related to marketing approvals of EYLEA™ in major market countries outside the U.S.

Fees paid to the federal government by pharmaceutical manufacturers

In December 2010, the FASB provided authoritative guidance on how pharmaceutical manufacturers should recognize and classify in their income statement annual fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act. This guidance became effective for calendar years beginning after December 31, 2010. The adoption of this guidance did not have an impact on the Company's financial statements as the fee does not currently apply to the Company. The Company's marketed product, ARCALYST® for the treatment of CAPS, has been approved as an orphan drug and orphan drugs are not subject to this annual fee.

Presentation of comprehensive income

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on the Company's financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among other things, the nature, timing, and possible success of and therapeutic applications for our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be canceled or terminated without any product success, and risks associated with third-party intellectual property and pending or future litigation relating thereto. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have 11 product candidates in clinical development, all of which were discovered in our research laboratories. Our late-stage (Phase 3) programs are:

- EYLEA™ (aflibercept injection), also known as VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of serious eye diseases;
- ZALTRAP™ (aflibercept), also known as VEGF Trap, which is being developed in oncology in collaboration with Sanofi; and
- ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment.

Our earlier stage clinical programs include the following fully human monoclonal antibodies:

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis;
- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and eosinophilic asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold);
- REGN728, an antibody in clinical development against an undisclosed target; and
- REGN846, an antibody in clinical development against an undisclosed target.

With the exception of REGN846, which we are developing independently, all of these antibodies are being developed in collaboration with Sanofi.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*®. Under the terms of our antibody collaboration with Sanofi, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® – CAPS

Net product sales of ARCALYST® (rilonacept) in the second quarter of 2011 were $5.0 million, compared to $5.2 million during the same quarter of 2010. ARCALYST® net product sales for the six months ended June 30, 2011 and 2010, respectively, totaled $9.5 million and $15.0 million. ARCALYST® net product sales during the first six months of 2010 included $10.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described below under "Results of Operations."

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST® is available for prescription in the U.S. for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. EYLEA™ (aflibercept injection) also known as VEGF Trap-Eye – Ophthalmologic Diseases

EYLEA™ (aflibercept injection) is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF) proteins that are involved in the abnormal growth of new blood vessels. We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating EYLEA™ in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared EYLEA™ and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-VEGF agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated EYLEA™ doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (following three initial monthly doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with EYLEA™ who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis®. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of EYLEA™, including EYLEA™ dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month.

A generally favorable safety profile was observed for both EYLEA™ and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in February 2011 for marketing approval of EYLEA™ in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA unanimously recommended that the FDA approve our BLA. Under Priority Review, the target date for an FDA decision on the EYLEA™ BLA is August 20, 2011. Also in June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA™ in wet AMD in the European Union and Japan.

EYLEA™ is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either EYLEA™ at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment as measured by the ETDRS eye chart. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

In December 2010, we and Bayer HealthCare announced that in the COPERNICUS study, EYLEA™ demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In the study, EYLEA™ was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the EYLEA™ group were uncommon (3.5%), consisting of individual reports of corneal abrasion, endophalmitis, retinal vein occlusion, and reduced visual acuity, and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with EYLEA™ and two (2.7%) in the 73 patients treated with sham injections.

In April 2011, we and Bayer HealthCare announced that in the GALILEO study, EYLEA™ also demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In this trial, 60.2% of patients receiving 2.0 mg of EYLEA™ monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). Patients receiving 2.0 mg of EYLEA™ monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

As in the COPERNICUS trial, EYLEA™ was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the EYLEA™ group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the EYLEA™ arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

Based on these positive results, we intend to submit a regulatory application for marketing approval for EYLEA™ in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in this indication in Europe in 2012.

In the second quarter of 2011, we and Bayer Healthcare initiated Phase 3 studies to evaluate the safety and efficacy of EYLEA™ in DME. These clinical trials have three study arms. In the first arm, patients will be treated every month with 2.0 mg of EYLEA™. In the second arm, patients will be treated with 2.0 mg of EYLEA™ every two months after an initial phase of monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint of the study is mean change in visual acuity from baseline as measured by the ETDRS eye chart. All patients will be followed for three years. We are conducting one of these studies, called VISTA-DME (VEGF Trap-Eye: Investigation of Safety, Treatment effect, and Anatomic outcomes in DME), with study centers in the U.S., Canada, India and Israel. Bayer Healthcare is conducting the second study, named VIVID-DME (VEGF Trap-Eye In Vision Impairment Due to DME), with study centers in Europe, Japan, and Australia.

In the first quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of EYLEA™ in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the U.S. of EYLEA™. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA™ through an integrated global plan. Bayer HealthCare will market EYLEA™ outside the U.S., where the companies will share equally in profits from any future sales of EYLEA™. Commencing on the first commercial sale of EYLEA™ in a major market country outside the U.S., we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. Within the U.S., we retain exclusive commercialization rights to EYLEA™ and are entitled to all profits from any such sales. We have received $60 million in development milestone payments and can earn up to $50 million in future milestone payments related to marketing approvals of EYLEA™ in major market countries outside the U.S. We can also earn up to $135 million in sales milestone payments if total annual sales of EYLEA™ outside the U.S. achieve certain specified levels starting at $200 million.

2. ZALTRAP™ (aflibercept) also known as VEGF Trap – Oncology

ZALTRAP™ (aflibercept) is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and PlGF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

ZALTRAP™ is being developed globally in cancer indications in collaboration with Sanofi. In April 2011, we and Sanofi announced that the Phase 3 VELOUR trial evaluating ZALTRAP™ in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in previously treated metastatic colorectal cancer (mCRC) patients. The VELOUR data were presented in June 2011 at the European Society of Medical Oncology World Congress on Gastrointestinal Cancer. In this study, the addition of ZALTRAP™ to the FOLFIRI chemotherapy regimen significantly improved both overall survival (HR=0.817; p=0.0032) and progression-free survival (HR=0.758; p=0.00007) compared to FOLFIRI plus placebo. A similar effect was seen with ZALTRAP™ therapy whether or not patients had received prior bevacizumab therapy.

In the VELOUR study, grade 3 or 4 adverse events (AEs) that occurred with a more than two percent greater incidence in the ZALTRAP™ arm than in the placebo arm included diarrhea, asthenia/fatigue, stomatitis/ulceration, infections, hypertension, GI/abdominal pains, neutropenia, neutropenic complications and proteinuria. Deaths on study treatment due to AEs occurred in 2.4 percent of patients in the ZALTRAP™ arm and in 1.0 percent of patients in the placebo arm.

Based upon these positive findings, we and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP™ for the treatment of previously-treated mCRC patients to the FDA and the European Medicines Agency (EMA) in the second half of 2011.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP™ as a first-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. The VENICE trial is being monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the trial and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in this trial. In July 2011, the study's IDMC met for a scheduled interim analysis and recommended that the trial continue to completion. Final results are anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) of ZALTRAP™ in first-line mCRC in combination with FOLFOX [folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin] is fully enrolled. Initial data from this study are anticipated in the second half of 2011.

ZALTRAP™ Collaboration with Sanofi

We and Sanofi globally collaborate on the development and commercialization of ZALTRAP™. Under the terms of our September 2003 collaboration agreement, as amended, we and Sanofi will share co-promotion rights and profits on sales, if any, of ZALTRAP™ outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of ZALTRAP™, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight ZALTRAP™ oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the ZALTRAP™ collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by Sanofi. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi out of our share of ZALTRAP™ profits for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAP™ profits in the quarter unless we elect to reimburse Sanofi at a faster rate.

3. ARCALYST® (rilonacept) – Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break-up of urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We conducted a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program consisted of three studies: PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations).

In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period.

In addition, all secondary endpoints of the study were highly positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88%. Treatment with ARCALYST® also reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65%.

In February 2011, we reported the results of PRE-SURGE 2 and RE-SURGE. In the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, which was identical to PRE-SURGE 1 in design and analysis, 248 patients were randomized. ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). Among secondary endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 82%. In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 63%.

We also announced that in the RE-SURGE study, which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. In the overall gout program, the most frequently reported adverse events were injection site reaction and headache.

In the RE-SURGE study, ARCALYST® also met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Based on the results of the three Phase 3 studies, we plan to submit in the second half of 2011 a supplemental BLA for U.S. regulatory approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We own worldwide rights to ARCALYST®.

4. Sarilumab (REGN88; IL-6R Antibody) for inflammatory diseases

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, Actemra® (tocilizumab), a registered trademark of Genentech, has been approved for the treatment of rheumatoid arthritis.

Sarilumab is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology. In July 2011, we and Sanofi announced that in the Phase 2b MOBILITY trial in rheumatoid arthritis (RA), patients treated with sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA compared to patients treated with MTX alone. The MOBILITY study is a 306-patient, dose-ranging, multi-national, randomized, multi-arm, double-blind, placebo-controlled study, that compared five different dose regimens of sarilumab in combination with MTX to placebo plus MTX. The primary endpoint of the study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks.

In the MOBILITY trial, there was a dose response observed in patients receiving sarilumab in combination with MTX. An ACR20 response after 12 weeks was seen in 49.0% of patients receiving the lowest sarilumab dose regimen and 72.0% of patients receiving the highest dose regimen compared to 46.2% of patients receiving placebo and MTX (p=0.02, corrected for multiplicity, for the highest sarilumab dose regimen). The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities. The types and frequencies of adverse events were consistent with those previously reported with IL-6 inhibition. The incidence of serious adverse events among the five sarilumab treatment groups and the placebo group was comparable.

Sarilumab also demonstrated significant benefit compared to placebo in secondary endpoints, including ACR 50, ACR 70, and DAS 28 scores, additional measures of clinical activity used in RA trials.

In July 2011, we and Sanofi announced that in the phase 2b ALIGN trial in ankylosing spondylitis (AS) sarilumab did not demonstrate significant improvements in the signs and symptoms of active AS compared to placebo in patients who had inadequate response to NSAIDs. Sarilumab was generally well tolerated. The most common adverse events reported more frequently in active treatment arms included infections and neutropenia.

Sarilumab is being developed in collaboration with Sanofi.

5. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune*® technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported.

During 2011, three Phase 2 studies with subcutaneous regimens of REGN727 have been initiated: (1) a randomized, double-blind, multi-dose, placebo controlled, 75-patient trial in patients with heterozygous familial hypercholesterolemia (heFH), (2) a randomized, double-blind, multi-dose, placebo controlled, 90-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia, and (3) a randomized, double-blind, multi-dose, placebo controlled, 180-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia and on stable doses of atorvastatin. The primary endpoint of each Phase 2 study is the change in LDL cholesterol from baseline compared to placebo over the study period.

REGN727 is being developed in collaboration with Sanofi.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune®* technology that is designed to bind to IL-4R. REGN668 is in a Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma. REGN668 is being developed in collaboration with Sanofi.

7. REGN421 (Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune®* technology, and is in Phase 1 clinical development. REGN421 is being developed in collaboration with Sanofi.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a Phase 1 study in an oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is a fully human monoclonal antibody generated using our *VelocImmune®* technology, which is being developed for cancer indications. REGN910 is being developed in collaboration with Sanofi.

9. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune®* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF.

In May 2010, we announced positive results from an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. On September 13, 2011, the FDA's Arthritis Advisory Committee will meet to discuss possible safety issues related to anti-NGF compounds. The FDA will ask the Committee to determine whether reports of joint destruction represent a safety signal for the class and whether the risk-benefit balance for these compounds favors continued development as analgesics. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with Sanofi.

10. REGN728

In the fourth quarter of 2010, clinical trials began with REGN728, a fully human monoclonal antibody generated using our *VelocImmune®* technology, against an undisclosed target. REGN728 is being developed in collaboration with Sanofi.

11. REGN846

In the fourth quarter of 2010, we and Sanofi initiated clinical trials with REGN846, a fully human monoclonal antibody generated using our *VelocImmune®* technology, against an undisclosed target. In July 2011, Sanofi elected not to continue co-development of REGN846, and Regeneron now has sole global rights to REGN846. Under the terms of our agreement, Sanofi remains obligated to fund REGN846 clinical costs through conclusion of a planned proof-of-concept trial and is entitled to receive a mid-single digit royalty on any future sales of REGN846.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as ZALTRAP™ and EYLEA™, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®*. The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune®* and our entire *VelociSuite™* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune®* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse®* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

Sanofi. In November 2007, we and Sanofi entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of $85.0 million from Sanofi. Pursuant to the collaboration, Sanofi is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified through discovery research under the discovery agreement, Sanofi has the option to license rights to the candidate under the license agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

Sanofi will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the U.S. The parties will share profits outside the U.S. on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and will share losses outside the U.S. at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the U.S. exceed $1.0 billion on a rolling 12-month basis.

In November 2009, we and Sanofi amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for Sanofi to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, Sanofi is also obligated to fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, Sanofi funded $137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement.

From the collaboration's inception in November 2007 through June 30, 2011, Sanofi has funded a total of $395.5 million of our costs under the discovery agreement and a total of $330.0 million of our development costs under the license agreement, or a total of $725.5 million in funding for our antibody research and development activities during this period.

In August 2008, we entered into an agreement with Sanofi to use our *VelociGene®* platform to supply Sanofi with genetically modified mammalian models of gene function and disease. Under this agreement, Sanofi is required to pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by Sanofi. Sanofi will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune*® technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. While our royalties under this agreement could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. We are unable to predict whether canakinumab will be approved for gout or any other indication in addition to CAPS, or whether, even if approved, canakinumab for such indication(s) will be successfully commercialized. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, $23.7 million has been received or is receivable from the grant's inception as of June 30, 2011 and we are entitled to receive an additional $1.6 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General:

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2011, we had a cumulative loss of $1.2 billion, principally related to our research and development activities. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. We submitted a BLA to the FDA in February 2011 for marketing approval of EYLEA™ in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the EYLEA™ BLA is August 20, 2011. In June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA™ in wet AMD in the European Union and in Japan. We plan to submit a BLA to the FDA in the second half of 2011 for marketing approval of EYLEA™ in CRVO in the U.S., and Bayer HealthCare is planning to submit regulatory applications for marketing approval of EYLEA™ in CRVO in Europe in 2012. We also plan to submit a supplemental BLA to the FDA in the second half of 2011 for marketing approval in the U.S. of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP™ for the treatment of patients with previously treated mCRC to the FDA and the EMA in the second half of 2011.

We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product(s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and development efforts, the progress of our efforts to commercialize our late-stage product candidates, the timing of certain expenses, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when our late-stage product candidates, including EYLEA™ in wet AMD, will receive regulatory approval or, if such approval is received, whether we will be able to successfully commercialize such product(s), or if we do commercialize such product(s), whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2011 to date were, and plans for the next 12 months are, as follows:

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
EYLEA™	• Submitted a BLA to the U.S. FDA for the treatment of wet AMD • FDA accepted BLA for wet AMD and granted our request for Priority Review • FDA Advisory Committee unanimously recommended FDA approval of BLA for the treatment of wet AMD • Bayer Healthcare submitted regulatory applications for marketing approval for EYLEA™ for the treatment of wet AMD in the European Union and in Japan • Reported positive six-month results in the Phase 3 GALILEO trial in CRVO • Initiated Phase 3 trials in DME in the U.S. and outside the U.S. • Bayer Healthcare initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia	• Target date for FDA decision on EYLEA™ BLA is August 20, 2011 • Report two-year data from VIEW 1 and VIEW 2 in wet AMD in the second half of 2011 • Report one-year data from COPERNICUS and GALILEO in CRVO in the second half of 2011 • Submit a BLA to the FDA for the treatment of CRVO in the second half of 2011

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
ZALTRAP™	• Presented positive results from the Phase 3 VELOUR trial in previously treated metastatic colorectal cancer (mCRC) patients • IDMC reviewed interim results for the Phase 3 VENICE trial in prostate cancer and recommended study continue to completion • Reported results for the VITAL trial in non-small cell lung cancer. ZALTRAP™ did not meet primary study endpoint.	• Submit a BLA to the FDA for the treatment of mCRC in the second half of 2011 • Report initial results in the Phase 2 AFFIRM trial in colorectal cancer in the second half of 2011
ARCALYST®	• Reported positive results from two Phase 3 studies for the prevention of gout flares (PRE-SURGE 2 and RESURGE)	• Submit a supplemental BLA to the FDA for the prevention of gout flares in the second half of 2011
Sarilumab (IL-6R Antibody)	• Reported positive Phase 2b data in rheumatoid arthritis • Reported that the Phase 2b trial in ankylosing spondylitis did not meet its primary endpoint	• Initiate the Phase 3 portion of the Phase 2/3 rheumatoid arthritis trial
REGN727 (PCSK9 Antibody)	• Initiated Phase 2 studies for LDL cholesterol reduction	• Report initial data from the Phase 2 program for LDL cholesterol reduction
REGN668 (IL-4R Antibody)	• Initiated Phase 1b study in atopic dermatitis and Phase 2 proof of concept study in eosinophilic asthma	• Initiate Phase 2 program in atopic dermatitis
REGN421 (Dll4 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate a Phase 1b program in advanced malignancies
REGN910 (ANG2 Antibody)	• Continued patient enrollment in Phase 1 program	
REGN475 (NGF Antibody)	• On clinical hold	
REGN728 (target not disclosed)	• Continued patient enrollment in Phase 1 program	
REGN846 (target not disclosed)	• Continued patient enrollment in Phase 1 program • Sanofi elected not to co-develop REGN846	

Results of Operations

Three Months Ended June 30, 2011 and 2010

Net Loss

Regeneron reported a net loss of $62.5 million, or $0.69 per share (basic and diluted), for the second quarter of 2011, compared to a net loss of $25.5 million, or $0.31 per share (basic and diluted), for the second quarter of 2010. The increase in our net loss in 2011 was principally due to higher research and development expenses and higher selling, general, and administrative expenses.

Revenues

Revenues for the three months ended June 30, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi	$ 84.5	$ 84.9
Bayer HealthCare	11.1	13.7
Total collaboration revenue	95.6	98.6
Technology licensing revenue	5.2	10.0
Net product sales	5.0	5.2
Contract research and other revenue	2.0	2.1
Total revenue	$ 107.8	$ 115.9

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP™ collaboration and $85.0 million related to the antibody collaboration.

Sanofi Collaboration Revenue	Three months ended June 30,	
(In millions)	2011	2010
ZALTRAP™:		
Regeneron expense reimbursement	$ 4.2	$ 3.8
Regeneron share of ZALTRAP™ commercialization expenses	(1.3)	
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total ZALTRAP™	5.4	6.3
Antibody:		
Regeneron expense reimbursement	76.6	76.4
Recognition of deferred revenue related to up-front and other payments	2.1	1.8
Recognition of revenue related to *VelocImmune*® agreement	0.4	0.4
Total antibody	79.1	78.6
Total Sanofi collaboration revenue	$ 84.5	$ 84.9

Sanofi's reimbursement of our ZALTRAP™ expenses increased in the second quarter of 2011 compared to same period in 2010, primarily due to higher costs related to manufacturing ZALTRAP™ clinical supplies. Effective in the second quarter of 2011, we and Sanofi began equally sharing pre-launch commercialization expenses related to ZALTRAP™ in accordance with the companies' collaboration agreement. Our share of these expenses was $1.3 million in the second quarter of 2011, which reduced our Sanofi collaboration revenue. As of June 30, 2011, $27.6 million of the original $105.0 million of up-front payments related to ZALTRAP™ was deferred and will be recognized as revenue in future periods.

In the second quarter of 2011, Sanofi's reimbursement of our antibody expenses consisted of $40.7 million under the discovery agreement and $35.9 million of development costs under the license agreement, compared to $36.6 million and $39.8 million, respectively, in the second quarter of 2010. The higher reimbursement amount under the discovery agreement in the second quarter of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities. The lower reimbursement of development costs in the second quarter of 2011, compared to the same period in 2010, was primarily due to REGN475, which is currently on clinical hold.

Recognition of deferred revenue related to Sanofi's $85.0 million up-front payment and other payments increased in the second quarter of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the performance period applicable to recognition of the original $85.0 million up-front payment. As of June 30, 2011, $25.5 million of such funding from Sanofi was received or receivable, compared to $14.3 million as of June 30, 2010; as a result, we recognized more deferred revenue in the second quarter of 2011 than in the same quarter of 2010. As of June 30, 2011, $77.8 million of the Sanofi payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with Sanofi. For both three months ended June 30, 2011 and 2010, we recognized $0.4 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron's global EYLEA™ development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Three months ended June 30,**	
(In millions)	**2011**	**2010**
Cost-sharing of Regeneron EYLEA™ development expenses	$ 8.6	$ 11.2
Recognition of deferred revenue related to up-front and other milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 11.1	$ 13.7

Cost-sharing of our global EYLEA™ development expenses with Bayer HealthCare decreased in the second quarter of 2011 compared to the same period in 2010. In the second quarter of 2011, we incurred lower clinical development costs in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 trial in DME. In connection with the recognition of deferred revenue related to the $75.0 million up-front payment and $20.0 million milestone payment received in August 2007, as of June 30, 2011, $42.0 million of these payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In connection with our *VelocImmune®* license agreement with AstraZeneca, which terminated effective as of February 2011, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably through February 2011. In the second quarter of 2011, we recognized $5.2 million of technology licensing revenue related to the Astellas agreement. In the second quarter of 2010, we recognized $10.0 million of technology licensing revenue related to the Astellas and AstraZeneca agreements. As of June 30, 2011, $163.5 million of technology licensing payments received from Astellas was deferred and will be recognized as revenue in future periods.

Net Product Sales

For the three months ended June 30, 2011 and 2010, we recognized as revenue $5.0 million and $5.2 million, respectively, of ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for both the three months ended June 30, 2011 and 2010 included $1.2 million recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $168.1 million in the second quarter of 2011 from $139.6 million in the second quarter of 2010. Our average headcount in the second quarter of 2011 increased to 1,497 from 1,214 in the same period of 2010 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi.

Operating expenses in the second quarter of 2011 and 2010 included a total of $12.4 million and $8.7 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended June 30, 2011		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 135.4	$ 7.7	$ 143.1
Selling, general, and administrative	19.9	4.7	24.6
Cost of goods sold	0.4		0.4
Total operating expenses	$ 155.7	$ 12.4	$ 168.1

	For the three months ended June 30, 2010		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 119.5	$ 5.0	$ 124.5
Selling, general, and administrative	11.0	3.7	14.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 130.9	$ 8.7	$ 139.6

The increase in total Non-cash Compensation Expense in the second quarter of 2011 was primarily attributable to (i) the recognition of higher expense in the second quarter of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to $143.1 million in the second quarter of 2011 from $124.5 million in the same period of 2010. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2011 and 2010:

Research and Development Expenses	**For the three months ended June 30,**		**Increase**
(In millions)	**2011**	**2010**	**(Decrease)**
Payroll and benefits (1)	$ 41.5	$ 31.9	$ 9.6
Clinical trial expenses	23.5	28.5	(5.0)
Clinical manufacturing costs (2)	30.0	27.6	2.4
Research and other development costs	15.8	13.8	2.0
Occupancy and other operating costs	15.0	12.7	2.3
Cost-sharing of Bayer HealthCare EYLEA™ development expenses (3)	17.3	10.0	7.3
Total research and development expenses	$ 143.1	$ 124.5	$ 18.6

(1) Includes $6.7 million and $4.2 million of Non-cash Compensation Expense for the three months ended June 30, 2011 and 2010, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.0 million and $0.8 million of Non-cash Compensation Expense for the three months ended June 30, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs global EYLEA™ development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's global EYLEA™ development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated global EYLEA™ development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its global EYLEA™ development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and our clinical development program for REGN475, which is currently on clinical hold. Clinical manufacturing costs increased primarily due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility, partly offset by lower costs related to manufacturing supplies of antibody candidates, including REGN475. Research and other development costs increased due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's global EYLEA™ development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the second quarter of 2011, and costs associated with ex-U.S. regulatory approval filings for EYLEA™ in wet AMD.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA™ development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**For the three months ended June 30,**		**Increase**
(In millions)	**2011**	**2010**	**(Decrease)**
ARCALYST®	$ 8.5	$ 11.6	$ (3.1)
EYLEA™	44.1	31.2	12.9
ZALTRAP™	4.0	3.0	1.0
Sarilumab	7.3	9.8	(2.5)
REGN727	9.7	6.0	3.7
Other antibody candidates in clinical development	15.4	20.2	(4.8)
Other research programs & unallocated costs	54.1	42.7	11.4
Total research and development expenses	$ 143.1	$ 124.5	$ 18.6

Drug development and approval in the U.S. is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, ZALTRAP™, and EYLEA™ in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors" under "Risks Related to the Development and Approval of Our Product Candidates," "Risks Related to Commercialization of Products," and "Regulatory and Litigation Risks." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $24.6 million in the second quarter of 2011 from $14.7 million in the same period of 2010 due primarily to increases in compensation expense and recruitment costs principally in connection with higher headcount in the second quarter of 2011, higher commercialization-related costs, primarily in connection with EYLEA™, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons described above.

Cost of Goods Sold

Cost of goods sold in both the second quarter of 2011 and 2010 was $0.4 million and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $1.0 million in the second quarter of 2011 from $0.6 million in the same period of 2010, due primarily to higher yields on, and higher average balances of, cash and marketable securities.

Interest expense increased to $4.0 million in the second quarter of 2011 from $2.3 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Six Months Ended June 30, 2011 and 2010

Net Loss

Regeneron reported a net loss of $106.0 million, or $1.18 per share (basic and diluted), for the first half of 2011, compared to a net loss of $56.0 million, or $0.69 per share (basic and diluted) for the first half of 2010. The increase in our net loss in 2011 was principally due to higher research and development expenses and higher selling, general, and administrative expenses.

Revenues

Revenues for the six months ended June 30, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi	$ 169.8	$ 153.6
Bayer HealthCare	23.6	26.7
Total collaboration revenue	193.4	180.3
Technology licensing revenue	13.0	20.1
Net product sales	9.5	15.0
Contract research and other revenue	4.1	4.0
Total revenue	$ 220.0	$ 219.4

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP™ collaboration and $85.0 million related to the antibody collaboration.

Sanofi Collaboration Revenue	**Six months ended June 30,**	
(In millions)	**2011**	**2010**
ZALTRAP™		
Regeneron expense reimbursement	$ 11.4	$ 8.7
Regeneron share of ZALTRAP™ commercialization expenses	(1.5)	
Recognition of deferred revenue related to up-front payments	5.0	5.0
Total ZALTRAP™	15.1	13.7
Antibody:		
Regeneron expense reimbursement	149.8	135.8
Recognition of deferred revenue related to up-front and other payments	4.1	3.3
Recognition of revenue related to *Velaclone*® agreement	0.8	0.8
Total antibody	154.7	139.9
Total Sanofi collaboration revenue	$ 169.8	$ 153.6

Sanofi's reimbursement of our ZALTRAP™ expenses increased in the first half of 2011 compared to the same period in 2010, primarily due to higher costs related to manufacturing ZALTRAP™ clinical supplies. Effective in the second quarter of 2011, we and Sanofi began equally sharing pre-launch commercialization expenses related to ZALTRAP™ in accordance with the companies' collaboration agreement. Our share of these expenses was $1.3 million in the first half of 2011, which reduced our Sanofi collaboration revenue.

In the first half of 2011, Sanofi's reimbursement of our antibody expenses consisted of $82.8 million under the discovery agreement and $67.0 million of development costs under the license agreement, compared to $63.4 million and $72.4 million, respectively, in the first half of 2010. The higher reimbursement amount under the discovery agreement in the first half of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities. The lower reimbursement of development costs in the second quarter of 2011, compared to the same period in 2010, was primarily due to REGN475, which is currently on clinical hold.

Recognition of deferred revenue related to Sanofi's $85.0 million up-front payment and other payments increased in the first half of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the performance period applicable to recognition of the original $85.0 million up-front payment.

In August 2008, we entered into a separate *VelociGene*® agreement with Sanofi. For both six months ended June 30, 2011 and 2010, we recognized $0.8 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron's global EYLEA™ development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Six months ended June 30,**	
(In millions)	**2011**	**2010**
Cost-sharing of Regeneron EYLEA™ development expenses	$ 18.7	$ 21.8
Recognition of deferred revenue related to up-front and other milestone payments	4.9	4.9
Total Bayer HealthCare collaboration revenue	$ 23.6	$ 26.7

Cost-sharing of our global EYLEA™ development expenses with Bayer HealthCare decreased in the first half of 2011 compared to the same period in 2010. In the first half of 2011, we incurred lower clinical development costs in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 DA VINCI trial in DME, partly offset by higher internal costs in connection with regulatory filings in wet AMD.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In connection with our *VelocImmune*® license agreement with AstraZeneca, which terminated effective as of February 2011, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably through February 2011. In the first half of 2011 and 2010, we recognized $13.0 million and $20.0 million, respectively, of technology licensing revenue related to these agreements.

Net Product Sales

For the six months ended June 30, 2011 and 2010, we recognized as revenue $9.5 million and $15.0 million, respectively, of ARCALYST® net product sales. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the six months ended June 30, 2010, we recognized as revenue $15.0 million of ARCALYST® net product sales, which included $10.2 million of ARCALYST® net product sales made during the period and $4.8 million of previously deferred net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the first half of 2011 and 2010 included $2.2 million and $2.3 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $321.3 million in the first half of 2011 from $272.0 million for the same period of 2010. Our average headcount in the first half of 2011 increased to 1,464 from 1,151 in the same period of 2010 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi.

Operating expenses in the first half of 2011 and 2010 included a total of $27.2 million and $17.5 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the six months ended June 30, 2011		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 257.0	$ 15.5	$ 272.5
Selling, general, and administrative	36.3	11.7	48.0
Cost of goods sold	0.8		0.8
Total operating expenses	$ 294.1	$ 27.2	$ 321.3

	For the six months ended June 30, 2010		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 232.0	$ 10.0	$ 242.0
Selling, general, and administrative	21.4	7.5	28.9
Cost of goods sold	1.1		1.1
Total operating expenses	$ 254.5	$ 17.5	$ 272.0

The increase in total Non-cash Compensation Expense in the first half of 2011 was primarily attributable to (i) the recognition of higher expense in the first half of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to $272.5 million in the first half of 2011 from $242.0 million for the same period of 2010. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2011 and 2010:

Research and Development Expenses	For the six months ended June 30,		Increase
(In millions)	2011	2010	(Decrease)
Payroll and benefits (1)	$ 84.1	$ 59.6	$ 24.5
Clinical trial expenses	42.5	60.8	(18.3)
Clinical manufacturing costs (2)	52.2	47.5	4.7
Research and other development costs	31.1	26.6	4.5
Occupancy and other operating costs	29.0	24.7	4.3
Cost-sharing of Bayer HealthCare EYLEA™ development expenses (3)	33.6	22.8	10.8
Total research and development expenses	$ 272.5	$ 242.0	$ 30.5

(1) Includes $13.6 million and $8.5 million of Non-cash Compensation Expense for the six months ended June 30, 2011 and 2010, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.9 million and $1.5 million of Non-cash Compensation Expense for the six months ended June 30, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs global EYLEA™ development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's global EYLEA™ development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated global EYLEA™ development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its global EYLEA™ development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and our clinical development program for REGN475, which is currently on clinical hold. Clinical manufacturing costs increased primarily due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility, partly offset by lower costs related to manufacturing supplies of antibody candidates, including REGN475. Research and other development costs increased primarily due to higher costs associated with our antibody programs and filing our BLA for EYLEA™ in wet AMD. Occupancy and other operating costs increased primarily principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's global EYLEA™ development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the second quarter of 2011, and costs associated with ex-U.S. regulatory approval filings for EYLEA™ in wet AMD.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA™ development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the six months ended June 30,		Increase
(In millions)	2011	2010	(Decrease)
ARCALYST®	$ 17.4	$ 31.7	$ (14.3)
EYLEA™	83.7	64.8	18.9
ZALTRAP™	10.4	6.9	3.5
Sarilumab	14.0	14.7	(0.7)
REGN727	16.8	11.2	5.6
Other antibody candidates in clinical development	28.0	39.1	(11.1)
Other research programs & unallocated costs	102.2	73.6	28.6
Total research and development expenses	$ 272.5	$ 242.0	$ 30.5

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2011 and 2010, and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $48.0 million in the first half of 2011 from $28.9 million for the same period of 2010 due primarily to increases in compensation expense and recruitment costs principally in connection with higher headcount in the first half of 2011, higher commercialization-related costs, primarily in connection with EYLEA™, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons described above.

Cost of Goods Sold

Cost of goods sold in the first half of 2011 and 2010 was $0.8 million and $1.1 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $2.0 million in the first half of 2011 from $1.0 million in the same period of 2010, due primarily to higher yields on, and higher average balances of, cash and marketable securities.

Interest expense increased to $7.8 million in the first half of 2011 from $4.4 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including Sanofi, revenue earned under our past and present research and development agreements, including our agreements with Sanofi and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Six months ended June 30, 2011 and 2010

At June 30, 2011, we had $569.1 million in cash, cash equivalents, and marketable securities (including $8.2 million of restricted cash and marketable securities) compared with $626.9 million at December 31, 2010 (including $7.5 million of restricted cash and marketable securities). In January 2011, we received, from Bayer HealthCare, a $10.0 million milestone payment, which was earned in 2010, in connection with the COPERNICUS study of EYLEA™ in CRVO.

Cash Used in Operating Activities

Net cash used in operating activities was $44.6 million in the first six months of 2011 and $21.4 million in the first six months of 2010. Our net losses of $106.0 million in the first half of 2011 and $56.0 million in the first half of 2010 included $27.2 million and $17.5 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $14.9 million and $8.7 million in the first half of 2011 and 2010, respectively.

At June 30, 2011, accounts receivable decreased by $8.5 million, compared to end-of-year 2010, primarily due to the receipt of the $10.0 million milestone payment in January 2011 from Bayer HealthCare, as discussed above. Prepaid expenses and other assets increased by $8.2 million, compared to end-of-year 2010, primarily due to increases in prepaid clinical trial costs and capitalized inventory supplies. Our deferred revenue at June 30, 2011 decreased by $20.6 million, compared to end-of-year 2010, primarily due to the amortization of previously received and deferred $20.0 million payments under our license agreements with AstraZeneca and Astellas, as well as amortization of previously received deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $38.6 million at June 30, 2011, compared to end-of-year 2010, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for pre-launch commercialization activities, higher payroll-related liabilities, and an $8.8 million increase in cost-sharing payments due to Bayer HealthCare in connection with our EYLEA™ collaboration.

At June 30, 2010, accounts receivable increased by $29.6 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with Sanofi. Also, our deferred revenue balances at June 30, 2010 increased by $16.6 million, compared to end-of-year 2009, primarily due to (i) the receipt of the $20.0 million annual payments from AstraZeneca and Astellas in the first half of 2010, which were deferred and recognized ratably over the ensuing year and (ii) Sanofi's funding of $13.8 million of agreed-upon costs incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment received from Sanofi. These increases were partially offset by amortization of previously received deferred payments under our Sanofi and Bayer HealthCare collaborations. At June 30, 2010, accounts payable, accrued expenses, and other liabilities increased by $18.1 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $163.3 million in the first six months of 2011, compared with net cash used in investing activities of $132.6 million in the first half of 2010. In the first half of 2011, sales or maturities of marketable securities exceeded purchases by $201.0 million, whereas in the first half of 2010, purchases of marketable securities exceeded sales or maturities by $85.5 million. Capital expenditures in the first half of 2011 and 2010 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased facilities in Tarrytown, New York.

Cash Provided by Financing Activities

Net cash provided by financing activities was $23.1 million in the first six months of 2011 and $58.9 million in the first six months of 2010. In the first half of 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with Financial Accounting Standards Board ("FASB") authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $23.8 million in the first six months of 2011 and $12.1 million in the first six months of 2010.

Fair Value of Marketable Securities

At June 30, 2011 and December 31 2010, we held marketable securities whose aggregate fair value totaled $314.7 million and $513.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	June 30, 2011		December 31, 2010	
Investment type	**Fair Value**	**Percent**	**Fair Value**	**Percent**
Unrestricted				
U.S. government agency securities	$ 237.2	75%	$ 434.4	85%
U.S. government-guaranteed corporate bonds	47.5	15%	64.0	13%
Municipal bonds	16.1	5%	1.6	
Equity securities	4.3	1%	3.6	1%
U.S. government guaranteed collateralized mortgage obligations	1.3	1%	2.1	
Mortgage-backed securities	0.2		1.1	
Total unrestricted marketable securities	306.6	97%	506.8	99%
Restricted				
U.S. government agency securities	8.1	3%	7.1	1%
Total marketable securities	$ 314.7	100%	$ 513.9	100%

In addition, at June 30, 2011 and December 31, 2010, we had $254.4 million and $113.0 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $37.0 million and $45.3 million for the first six months of 2011 and 2010, respectively. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, Sanofi has funded $2.1 million and $13.8 million, respectively, of agreed-upon capital expenditures incurred by us during the first half of 2011 and 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at June 30, 2011 and 2010.

We expect to incur capital expenditures of approximately $35 to $55 million during the remainder of 2011 primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by Sanofi, with the remaining amount to be funded by our existing capital resources.

Funding Requirements

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our ZALTRAP™ and antibodies collaborations are, generally, fully funded by Sanofi. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our EYLEA™ collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 30-40% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and EYLEA™). For 2011, we also currently estimate that approximately 15-25% of our funding requirements will be directed toward the planned commercialization of our late-stage product candidates; approximately 20-30% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with Sanofi and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, whether or not our late-stage product candidates receive regulatory approval, the market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credit totaling $4.2 million, including a $3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2011, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure additional funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In December 2010, the FASB provided authoritative guidance on how pharmaceutical manufacturers should recognize and classify in their income statement annual fees mandated by the Patient Protection and Affordable Care Act (PPACA) as amended by the Health Care and Education Reconciliation Act. This guidance became effective for calendar years beginning after December 31, 2010. The adoption of this guidance did not have an impact on our financial statements as the fee does not currently apply to us. Our one marketed product, ARCALYST® for the treatment of CAPS, has been approved as an orphan drug and orphan drugs are not subject to this annual fee.

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. We will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $1.4 million and $1.2 million decrease in the fair value of our unrestricted investment portfolio at June 30, 2011 and 2010, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at June 30, 2011 compared to the same period of 2010.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in the first six months of 2010. During the first six months of 2011, we did not recognize any other-than-temporary impairment charges.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current ordinary course legal proceedings to have a material adverse effect on our business or financial condition.

As previously reported, on November 19, 2010, we filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to our VEGF Trap (aflibercept) infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon our submission to the FDA of a BLA for EYLEA™ (aflibercept injection) for the treatment of wet AMD, we filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, we and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, we voluntarily dismissed our original complaint in favor of proceeding with our second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, we replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of our prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. We believe Genentech's counterclaims are without merit and intend to continue to defend against them vigorously.

We have initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2011, we had a cumulative loss of $1.2 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of those product(s). We believe our existing capital resources, together with funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase, which could result in our capital being consumed significantly before that time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our late-stage product candidates, expenses related to clinical trials testing ARCALYST® or EYLEA™, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with Sanofi.

We may require additional financing in the future and we may not be able to raise additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs. Even if we obtain regulatory approval for our product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of June 30, 2011, our cash, cash equivalents, and marketable securities totaled $569.1 million (including $8.2 million of restricted cash and marketable securities). We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $306.6 million at June 30, 2011, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. The current economic environment and the volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to the Development and Approval of Our Product Candidates

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of EYLEA™ for the treatment of wet AMD and other ophthalmologic diseases, which has not yet been approved by the FDA or by regulatory authorities in countries outside the U.S. If there are material delays in obtaining marketing approval for EYLEA™, or such approval is not obtained, our business, results of operations, and financial condition will be materially harmed.

The FDA has substantial discretion in deciding whether or not EYLEA™ should be granted approval in the U.S. based on the benefits and risks of EYLEA™ in treating the particular ophthalmologic diseases in which it is being studied in clinical trials. In February 2011, we submitted a BLA for EYLEA™ for the treatment of wet AMD to the FDA. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the BLA is August 20, 2011. However, the FDA is not under any legal obligation to complete its review of the BLA or to render a decision within this timeframe, and it is not unusual for the FDA's review of and/or rendering a decision with respect to a BLA that has been granted Priority Review to extend beyond the initial target date. For instance, the FDA may request additional clinical or other data or information, including by issuing a complete response letter which may require that we submit additional clinical or other data or impose other conditions that must be met in order to secure final approval of our BLA. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The granting of Priority Review designation for our BLA does not change the standards for approval and does not ensure that EYLEA™ for the treatment of wet AMD will be approved. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA voted unanimously to recommend that the FDA approve EYLEA™ for the treatment of wet AMD at a dose of 2 milligrams every eight weeks following three initial doses given every four weeks. The FDA will consider the committee's recommendation in its review of our BLA, but it is not bound by the committee's recommendation and there can be no assurance that the FDA will follow the committee's recommendation.

Whether EYLEA™ is approved by the FDA for the treatment of wet AMD, and the timing thereof, will depend on many factors, including the following:

- whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of EYLEA™ demonstrates that it is safe and effective as a treatment for wet AMD;
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for EYLEA™ are adequate, that the labeling is satisfactory, and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient; and
- the timing and nature of the FDA's comments and questions, or those of any advisers to the FDA if the FDA seeks external advice, regarding our BLA for EYLEA™ for the treatment of wet AMD, the time required to respond to any such comments and questions and to obtain final labeling, and any other delays that may be associated with the BLA review process.

In June 2011, Bayer Healthcare submitted regulatory applications for marketing approval of ELYEA™ in wet AMD in the European Union and Japan. Analogous regulatory authorities in these and other countries outside the U.S. have similar discretion to the FDA as to approval of EYLEA™ in those countries.

If we experience material delays in obtaining marketing approval for EYLEA™ for wet AMD, we will not receive product revenues during the delay, which would negatively affect our business, results of operations, and financial condition. Such delays may also increase the challenge of competitive products as doctors and patients continue to use existing therapies. If we do not obtain approval to market EYLEA™ for wet AMD, or if there are material delays in obtaining such approval, our business and financial position will be materially harmed.

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them, which would materially and negatively impact our business and prospects.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, EYLEA™ for the treatment of ophthalmologic diseases, and/or ZALTRAP™ for one or more oncology indications, the value of our company and our results of operations will be materially harmed. As with our BLA for EYLEA™ for the treatment of wet AMD, we cannot predict as to whether or when our other product candidates, including ZALTRAP™ for previously treated mCRC, EYLEA™ for CRVO and DME, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, will receive regulatory approval. If we are unable to obtain such approval(s), or if we are materially delayed in doing so, our business and prospects would be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the U.S., we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for FDA approval of ARCALYST®, and the EMA approval of rilonacept, for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the U.S. or any other country. We may never receive regulatory approval for any of our current or future product candidates.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs and could substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the shipment and storage of the product. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, and following approval in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the U.S., we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process and requirements include all of the risks associated with FDA approval as well as country specific regulations, and actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Whether or not we obtain FDA approval for a product in the U.S., we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, regulatory approval for our product candidates may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GCPs. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon that drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, financial condition, and results of operations may be materially harmed.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are testing ZALTRAP™ and EYLEA™ in a number of late-stage clinical trials in various indications and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials.

In April 2011 we announced that our Phase 3 VELOUR trial of ZALTRAP™ met its primary endpoint of improving overall survival in the treatment of previously treated mCRC, and that based upon these positive results, we and Sanofi plan to submit regulatory applications for marketing approval to the FDA and EMA in the second half of 2011. However, we can give no assurance as to whether or when such applications, if submitted, will be approved. ZALTRAP™ is also in a Phase 3 clinical trial in combination with a standard chemotherapy regimen for the treatment of first-line androgen independent prostate cancer. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that ZALTRAP™ will be safe or effective in this cancer setting. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (Bevacizumab Injection), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of ZALTRAP™ in prostate cancer.

We are testing EYLEA™ in Phase 3 trials for the treatment of wet AMD, the treatment of CRVO, and the treatment of DME. As described above, in February 2011, we submitted a BLA to the FDA for marketing approval of EYLEA™ in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Although we reported positive Phase 3 trial results with EYLEA™ in wet AMD after one year of treatment, the Phase 3 trials will continue for an additional year and there is a risk that the results from the second year of the studies could differ from the previously reported results; such difference could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval.

We also reported positive Phase 3 trial results with EYLEA™ in CRVO after six months of treatment and, based on these results, plan to submit a regulatory application for marketing approval of EYLEA™ in CRVO in the second half of 2011. However, these trials are not all completed, and there is a risk that one-year results could differ from six-month results, and such final results could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval. There can be no assurance as to if or when we will receive regulatory approval for EYLEA™ in CRVO.

We also reported positive results of a Phase 2 trial of EYLEA™ for the treatment of DME and that we have initiated a Phase 3 program in that indication. A number of other potential new drugs and biologics which showed promising results in Phase 1 and 2 clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals, and this could occur with respect to subsequent clinical trials of EYLEA™ for the treatment of DME.

Based on the results of three Phase 3 studies, we plan to submit a supplemental BLA to the FDA seeking approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. However, there can be no assurance as to if or when the FDA will grant such approval. For example, in June 2011, following two positive Phase 3 trials, the Arthritis Advisory Committee of the FDA, voted to recommend against approval in a gout indication for Ilaris® (canikinumab), Novartis' IL-1 inhibitor which works through a similar mechanism as ARCALYST®.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP™ as a first-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of ARCALYST® for the treatment of CAPS and in clinical trials of some of our product candidates, and may also occur with the more widespread use of ZALTRAP™, EYLEA™, and/or ARCALYST® for the prevention of gout flares if they receive regulatory approval, which could cause our regulatory approval(s) to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or if the product candidate has received regulatory approval such approval may be revoked, which would severely harm our business.

ZALTRAP™ is being studied for the potential treatment of certain types of cancer and our EYLEA™ candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAP™ and EYLEA™ in each of the indications for which we are studying these product candidates. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including ZALTRAP™ delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like EYLEA™, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development and/or commercialization of ZALTRAP™ for the treatment of cancer or EYLEA™ for the treatment of diseases of the eye.

As more patients begin to use ARCALYST® if it receives approval for the prevention of gout flares in patients initiating uric acid-lowering therapy, and to the extent it is tested in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Ilaris® (canakinumab), a registered trademark of Novartis, Kineret® (anakinra), a registered trademark of Biovitrum AB, Enbrel® (etanercept), a registered trademark of Amgen, Inc. and Pfizer Inc., and Remicade® (infliximab) a registered trademark of Centocor Ortho Biotech, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. As noted above, in June 2011, following two positive Phase 3 trials, the Arthritis Advisory Committee of the FDA, voted to recommend against approval in a gout indication for Ilaris®, Novartis' IL-1 inhibitor which works through a similar mechanism as ARCALYST®.

Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in the current or future approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. On September 13, 2011, the FDA's Arthritis Advisory Committee will meet to discuss possible safety issues related to anti-NGF compounds. The FDA will ask the Committee to determine whether reports of joint destruction represent a safety signal for the class and whether the risk-benefit balance for these compounds favors continued development as analgesics. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our own employees, our collaborators or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the U.S. may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third-party patents or other proprietary rights, and the costs and expenses of ongoing patent litigation have been and will likely continue to be significant.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune®* technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of issued patents and pending patent applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAP™ or EYLEA™ infringe any valid claim in these patents or patent applications. As described above under Part II, Item 1 ("Legal Proceedings"), in November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York, seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. In April 2011, we and Genentech entered into a Joint Stipulation whereby Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the case for lack of subject matter jurisdiction. On April 25, 2011, Genentech filed an answer to our complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to our VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, we replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of our prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. We believe Genentech's counterclaims are without merit and intend to continue to defend against them vigorously. However, it is possible that there could be an adverse determination or judgment in this litigation that would materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of ZALTRAP™ or EYLEA™, or resulting in a damage award. In addition, irrespective of the outcome of this litigation, we have incurred and will likely continue to incur significant costs and expenses associated with this matter, which has negatively affected, and will likely continue to negatively affect, our results of operations. We have initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S., which could have similar or other adverse outcomes that would materially harm our business and which, irrespective of the outcomes, may also entail significant costs and expenses.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that sarilumab infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover sarilumab.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, ZALTRAP™, nor EYLEA™ are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the U.S.

Further, we are aware of a number of other third-party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing or selling our product candidates will not infringe such patents.

Patent holders in addition to Genentech could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our drug candidates, including EYLEA™ or our other late-stage product candidates, infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can be very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the U.S or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under *"If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed"*, the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could be material to us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the U.S. and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed which could result in substantial and rapid reductions in revenues from sales of those products.

Under the PPACA, enacted in 2010, there is now a new, abbreviated path in the U.S. for regulatory approval of biosimilar versions of biological products. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this new regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

We have and rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to successfully commercialize our products if they receive regulatory approval and also to continue to develop our clinical candidates.

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA™, ZALTRAP™, and ARCALYST® for the treatment of gout flares in sufficient commercial quantities if these late-stage product candidates were all to receive regulatory approval, and (b) our earlier stage product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. We rely entirely on third-parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to manufacture and supply sufficient commercial quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, third-party manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products, our business, financial condition, and results of operations may be materially harmed.

Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our late-stage product candidates if they are approved for marketing and could jeopardize our current and future clinical development programs.

Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our manufacturing and supply chain operations. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize EYLEA™, ZALTRAP™, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment if they receive regulatory approval, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, financial condition, and results of operations could be materially harmed.

Our ability to manufacture our products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe third-party patents.

Our ability to continue to manufacture ARCALYST®, EYLEA™, and ZALTRAP™ in our Rensselaer, New York facilities, or to utilize third-parties to produce our products or perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products which could materially harm our business, operations and prospects.

If the launch of our late-stage product candidates, or any of our clinical programs, are delayed or discontinued, we may face costs related to unused capacity at our manufacturing facilities and at the facilities of third parties performing fill/finish services or other steps in our manufacture and supply chain.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product of ARCALYST® for the treatment of CAPS and of clinical and preclinical candidates for ourselves and our collaborations, and plan to use such facilities to produce bulk product for commercial supply of our late-stage product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of our late-stage product candidates is delayed or does not occur, or if such products are launched and subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing fill/finish services for us.

Third-party service or supply failures, or other failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Also, certain raw materials necessary for the manufacture and formulation of ARCALYST® and of our product candidates, including EYLEA™ and ZALTRAP™, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of ARCALYST® and our product candidates. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® for the treatment of CAPS and to manufacture and supply commercial quantities of EYLEA™, ZALTRAP™, and ARCALYST® for the prevention of gout flares if they receive regulatory approval, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third-party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple product candidates at our facility in Rensselaer, New York, including ARCALYST®, EYLEA™, and ZALTRAP™, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business and prospects. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business and financial condition.

Risks Related to Commercialization of Products

Even if we receive regulatory approval to market EYLEA™ or our other late-stage product candidates, we may be unsuccessful in commercializing them, which would materially delay or prevent our achieving profitability.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture and commercialize those products. Even if we obtain regulatory approval for our product candidates, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, results of operations, and financial condition would be severely harmed.

In particular, we cannot be sure that EYLEA™ for the treatment of wet AMD will be commercially successful in the pharmaceutical market even if we obtain marketing approval for EYLEA™ for such indication in a timely manner. In addition to the challenges we face related to a company launching its first major commercial drug, as described in detail in the risk factor immediately below, we and Bayer Healthcare will face intense competition from Lucentis® and from off-label use of Avastin®, both of which have been on the market for a number of years. We expect that the initial commercial success of EYLEA™ for the treatment of wet AMD if it is approved for marketing will depend on many factors, including the following:

- the effectiveness of our and Bayer Healthcare's commercial strategy for the launch and marketing of EYLEA™ in and outside the U.S., respectively, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA™ with third-parties who perform fill/finish or other steps in the manufacture of EYLEA™ to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA™;
- our ability to effectively communicate to the marketplace the benefits of EYLEA's™ dosing regimen of every 2 months as compared to the monthly dosing regimen of Lucentis®, and the willingness of retinal specialists and patients to switch from Lucentis® or off-label use of Avastin® to EYLEA™ for the treatment of wet AMD;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payors, including Medicare and Medicaid in the U.S. and other government payors; and
- the effect of new health care legislation currently being implemented in the United States.

While we believe that EYLEA™ for the treatment of wet AMD will have a commercially competitive profile, we cannot predict whether ophthalmologists, particularly retinal specialists, and patients, will accept or utilize EYLEA™. Our and Bayer Healthcare's efforts to educate the relevant medical community and third-party payors regarding the benefits of EYLEA™ for the treatment of wet AMD will require significant resources and may not be successful in achieving our objectives. If EYLEA™ is approved for marketing but does not achieve significant market acceptance for the treatment of wet AMD, our ability to achieve profitability would be materially impaired or delayed.

If we are unable to establish and effectively deploy and manage sales, marketing, and distribution capabilities in the applicable markets or to enter into agreements with third parties to do so, even if our late-stage product candidates receive regulatory approval we will be unable to successfully launch and commercialize those products in those markets, which would materially harm our business, operating results, and financial condition.

We are selling ARCALYST® ourselves in the U.S. for the treatment of CAPS, primarily through third-party service providers. We are establishing our own sales, marketing, and distribution organization in anticipation of receiving regulatory approval to market and sell EYLEA™ in the U.S. for the treatment of wet AMD, and in anticipation of filing for and receiving regulatory approval to market and sell EYLEA™ in the U.S. for the treatment of CRVO. However, even if we can fully establish this organization in a timely fashion, we may be unsuccessful in achieving a successful launch and commercialization of EYLEA™ in the U.S., which would materially harm our business, operating results, and financial condition.

We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if it receives regulatory approval. If we are unable to obtain these capabilities, either by developing our own organizations or entering into agreements with others to provide these functions, even if ARCALYST® for the prevention of gout flares receives marketing approval, we will not be able to successfully launch and commercialize this product, which would also materially harm our business, operating results, and financial condition.

We have no experience in sales, marketing, or distribution of products in substantial commercial quantities or in establishing and managing the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network, and we may be unable to establish such infrastructure on a timely basis. In building a field force in anticipation of the possible approval and launch in the U.S. of EYLEA™ in wet AMD and other ophthalmologic indications for which it is currently in Phase 3 clinical trials, we may be unable to successfully recruit and retain within the required time frame an adequate number of qualified sales representatives. To the extent we determine to utilize third parties to provide sales, marketing, or distribution capabilities for ARCALYST® for the prevention of gout flares or any of our other products if they receive regulatory approval, we may encounter difficulties in retaining such parties on acceptable terms. Even if we hire qualified sales and marketing personnel, and establish the required infrastructure we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell in the U.S. EYLEA™, ARCALYST® for the prevention of gout flares, or any of our other product candidates if they receive regulatory approval in the U.S. and as to which we retain sales and marketing responsibility in that market. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining a sales force and distribution capabilities may be disproportional, particularly in the near term, compared to the revenues we may be able to generate on sales in the U.S. of EYLEA™ or ARCALYST® for the prevention of gout flares. We cannot guarantee that we or our collaborators will be successful in commercializing EYLEA™, ZALTRAP™, ARCALYST® for the prevention of gout flares, or any of our other product candidates.

Under the terms of our collaboration agreement, Sanofi has primary responsibility for sales, marketing, and distribution of ZALTRAP™ in cancer indications, should it be approved in the future by regulatory authorities for marketing.

We currently have no sales, marketing, commercial, or distribution capabilities outside the U.S. Under the terms of our license and collaboration agreement with Bayer HealthCare, we will rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA™ in countries outside the U.S. should it be approved for marketing in such countries.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain given their method of administration, and because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

As previously noted, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Some of these molecules are further along in development than ZALTRAP™ and may offer competitive advantages over our molecule. Each of Pfizer, Onyx Pharmaceuticals, Inc. (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin®, and their extensive, ongoing clinical development plan for Avastin® in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support ZALTRAP™ for those indications and to obtain regulatory approval of ZALTRAP™ in those indications. This may delay or impair our ability to successfully develop and commercialize ZALTRAP™ for various cancer indications. In addition, even if ZALTRAP™ is approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® for the treatment of wet AMD, CRVO, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following retinal vein occlusion (RVO), CRVO, and branch retinal vein occlusion (BRVO). Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as siRNAs that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin®.

The NEI and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT), were reported in April 2011 and indicated that Avastin® dosed monthly was non-inferior to Lucentis® dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Even if our BLA for EYLEA™ for the treatment of wet AMD is approved, it may be difficult for EYLEA™ in this or other eye indications for which it may be approved to compete against Lucentis® and Avastin® because doctors and patients have had significant experience using these medicines. Moreover, the recently reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA™ will face in this or other eye indications for which it may be approved. In addition, while we believe that ZALTRAP™ would not be well tolerated if administered directly to the eye, if ZALTRAP™ is approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage ZALTRAP™ for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA™ if it is approved for wet AMD or other eye indications.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel®, Remicade®, Humira® (adalimumab), a registered trademark of Abbott Laboratories, Simponi® (golimumab), a registered trademark of Centocor, the IL-1 receptor antagonist Kineret®, Ilaris® (canakinumab), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in indications other than CAPS, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients have had significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma Ltd. (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the U.S. and Europe for Ilaris®, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. Ilaris® is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, Ilaris® is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for the treatment of CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and plan to submit a BLA for U.S. regulatory approval in the second half of 2011. In January 2011, Novartis announced that the results of two Phase 3 studies with Ilaris® focused on reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout were positive. Novartis has also reported that regulatory filings for the use of Ilaris® in gouty arthritis have been completed in the European Union in 2010 and in the U.S. in the first quarter of 2011, based on the results of these two Phase 3 studies. Ilaris® is dosed less frequently for the treatment of CAPS, and if it is approved for the treatment of gout, it may be perceived by some physicians as offering competitive advantages over ARCALYST®, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other Nonsteroidal anti-inflammatory drugs (NSAIDS), are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST® in these diseases.

Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune®* technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor/Johnson & Johnson, and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects.

The successful commercialization of our late-stage product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the U.S., and these payers may not agree to cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, operating results, and financial condition.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDS. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected in a material manner if U.S. and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services (CMS) and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since EYLEA™ for the treatment of wet AMD and other eye diseases, ZALTRAP™ for oncology indications, and ARCALYST® for the prevention of gout flares will likely be too expensive for most patients to afford without health insurance coverage, if these products are approved for marketing but are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the U.S., our ability to successfully commercialize these products would be materially adversely impacted. We can provide no assurance that third-party payers, including Medicare and Medicaid in the U.S., will cover and/or reimburse for these products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Regulatory and Litigation Risks

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved product, ARCALYST® for the treatment of CAPS, or EYLEA™, ZALTRAP™, or ARCALYST® for the prevention of gout flares if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of our third-party fill/finish or other providers. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell approved products, in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the PPACA pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the Public Company Accounting Oversight Board (PCAOB), the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation (so-called "say on pay") and proxy access. On January 25, 2011, the SEC adopted final rules concerning "say on pay". Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2010, which report is included in our Annual Report on Form 10-K for the fiscal year ended on that date. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with Sanofi is terminated, our business operations and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from Sanofi to support our target discovery and antibody research and development programs. Sanofi has committed to pay up to $160 million per year, or a total of $1.28 billion, between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. Sanofi has a one-time option to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. If this downward adjustment occurs, it will reduce our resources available for antibody discovery activities and negatively affect our clinical pipeline. Sanofi also initially funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that Sanofi elects to co-develop with us. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us, such as REGN727, sarilumab, REGN668, REGN421, REGN910, REGN475, and REGN728, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the U.S. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. If Sanofi terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with Sanofi for ZALTRAP™ is terminated, or Sanofi materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize ZALTRAP™ in the time expected, or at all, would be materially harmed.

We rely heavily on Sanofi to lead much of the development of ZALTRAP™. Sanofi initially funds all of the development expenses incurred by both companies in connection with the ZALTRAP™ program. If the ZALTRAP™ program continues, we will rely on Sanofi to assist with funding the ZALTRAP™ program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the U.S., and lead the commercialization of ZALTRAP™. While we cannot assure you that ZALTRAP™ will ever be successfully developed and commercialized, if Sanofi does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize ZALTRAP™ in cancer indications will be significantly adversely affected. Sanofi has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If Sanofi were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of ZALTRAP™ and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the Sanofi collaboration agreement for ZALTRAP™ would create substantial new and additional risks to the successful development and commercialization of ZALTRAP™.

If our collaboration with Bayer HealthCare for EYLEA™ is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to continue to develop EYLEA™ and commercialize EYLEA™ outside the U.S. in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development, and the commercialization outside the U.S., of EYLEA™. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global EYLEA™ development program. As the EYLEA™ program continues, we will continue to rely on Bayer HealthCare to assist with funding the EYLEA™ development program, continue to lead the development of EYLEA™ outside the U.S., obtain regulatory approval outside the U.S., and provide all sales, marketing, and commercial support for the product outside the U.S. In particular, Bayer HealthCare has responsibility for selling EYLEA™ outside the U.S. using its sales force. While we cannot assure you that EYLEA™ will receive regulatory approval in or outside the U.S. or be successfully commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA™ outside the U.S. will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA™ outside the U.S. and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the U.S. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA™, particularly outside the U.S.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers, fill/finish, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates, and will also depend on some of these third parties in connection with the commercialization of our late-stage product candidates if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, Good Laboratory Practices (GLPs), or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for and successfully commercializing, our product candidates.

We rely on third-party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our sales of ARCALYST® for the treatment of CAPS will suffer.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we prepare for commercialization in the U.S. of our late-stage product candidates should they receive regulatory approval, we will also be highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion, and computer viruses which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our currently pending or future application(s) for regulatory approval of our late-stage product candidate(s);
- announcement of submission of an application for regulatory approval of one or more of our late-stage product candidates;
- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results; in particular, if EYLEA™ or any of our other late-stage product candidates is approved for marketing, and our revenues, market share, and/or market acceptance of EYLEA™ or such other products do not meet the expectations of investors or analysts;
- third-party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of any of our product candidates, including EYLEA™, ZALTRAP™, or ARCALYST® for the prevention of gout flares;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 13, 2011, our five largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 55.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 13, 2011. In September 2003, Sanofi (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 Sanofi purchased an additional 12,000,000 newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with Sanofi, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, Sanofi purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of April 13, 2011, Sanofi beneficially owned 15,816,953 shares of our Common Stock, representing approximately 17.8% of the shares of Common Stock then outstanding. If Sanofi, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2011, holders of Class A Stock held 19.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 13, 2011:

- our current executive officers and directors beneficially owned 12.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2011, and 25.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2011; and
- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 55.0% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 13, 2011. In addition, these six shareholders held 59.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 13, 2011.

Pursuant to an investor agreement, as amended, Sanofi has agreed to vote its shares, at Sanofi's election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with Sanofi, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder", a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with Sanofi or our ZALTRAP™ collaboration with Sanofi, Sanofi will be bound by certain "standstill" provisions, as amended, which contractually prohibit Sanofi from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of our company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of our company. Many of our stock options issued under our 2000 Long-Term Incentive Plan, as amended and restated, may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1(a) +	- Second Amended and Restated 2000 Long-Term Incentive Plan
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	- Interactive Data File
101.INS	- XBRL Instance Document
101.SCH	- XBRL Taxonomy Extension Schema
101.CAL	- XBRL Taxonomy Extension Calculation Linkbase
101.LAB	- XBRL Taxonomy Extension Label Linkbase
101.PRE	- XBRL Taxonomy Extension Presentation Linkbase
101.DEF	- XBRL Taxonomy Extension Definition Document

(a) Incorporated by reference from the Form S-8 for Regeneron Pharmaceuticals, Inc., filed June 13, 2011.

\+ Indicates a compensatory plan or arrangement.

(b) **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: July 28, 2011

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Exhibit 31.1

Certification of CEO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 28, 2011

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 28, 2011

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Exhibit 32

Certification of CEO and CFO Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
July 28, 2011

/s/ MURRAY A. GOLDBERG
Murray A. Goldberg
Chief Financial Officer
July 28, 2011

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 10/27/2011

Copyright © 2020 LexisNexis. All rights reserved.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2011

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road Tarrytown, New York	10591-6707
(Address of principal executive offices)	(Zip Code)

(914) 347-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X Accelerated filer ____
Non-accelerated filer ____ (Do not check if a smaller reporting company) Smaller reporting company ____

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes _____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of October 19, 2011:

Class of Common Stock	Number of Shares
Class A Stock, $0.001 par value	2,109,512
Common Stock, $0.001 par value	90,466,178

REGENERON PHARMACEUTICALS, INC.
Table of Contents
September 30, 2011

		Page Numbers
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed balance sheets (unaudited) at September 30, 2011 and December 31, 2010	3
	Condensed statements of operations (unaudited) for the three and nine months ended September 30, 2011 and 2010	4
	Condensed statements of stockholders' equity (unaudited) for the nine months ended September 30, 2011 and 2010	5
	Condensed statements of cash flows (unaudited) for the nine months ended September 30, 2011 and 2010	6
	Notes to condensed financial statements (unaudited)	7-17
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	18-45
Item 3	Quantitative and Qualitative Disclosures About Market Risk	46
Item 4	Controls and Procedures	46
PART II	**OTHER INFORMATION**	
Item 1	Legal Proceedings	46-47
Item 1A	Risk Factors	47-70
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	70
Item 6	Exhibits	70
SIGNATURE PAGE		71

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2011 AND DECEMBER 31, 2010 (Unaudited)
(In thousands, except share data)

	September 30, 2011	December 31, 2010
ASSETS		
Current assets		
Cash and cash equivalents	$ 206,395	$ 112,573
Marketable securities	39,103	136,796
Accounts receivable from Sanofi	74,788	79,603
Accounts receivable - other	3,659	13,509
Prepaid expenses and other current assets	15,927	15,142
Total current assets	339,872	357,622
Restricted cash and marketable securities	8,150	7,518
Marketable securities	258,073	370,053
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	364,913	347,450
Other assets	13,023	6,789
Total assets	$ 983,031	$ 1,089,432
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 78,890	$ 53,638
Deferred revenue from Sanofi, current portion	19,819	19,506
Deferred revenue - other, current portion	33,606	35,217
Facility lease obligations, current portion	920	675
Total current liabilities	133,235	109,036
Deferred revenue from Sanofi	88,033	97,081
Deferred revenue - other	166,623	188,775
Facility lease obligations	159,482	159,355
Other long term liabilities	7,405	7,350
Total liabilities	554,778	561,617
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none		
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,109,512 in 2011 and 2,182,036 in 2010	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 90,418,871 in 2011 and 87,238,301 in 2010	90	87
Additional paid-in capital	1,643,772	1,575,780
Accumulated deficit	(1,213,880)	(1,045,563)
Accumulated other comprehensive loss	(1,731)	(2,491)
Total stockholders' equity	428,253	527,815
Total liabilities and stockholders' equity	$ 983,031	$ 1,089,432

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2011	**2010**	**2011**	**2010**
Revenues				
Sanofi collaboration revenue	$ 79,802	$ 75,583	$ 249,577	$ 229,195
Other collaboration revenue	10,094	13,761	33,698	40,483
Technology licensing	5,893	10,037	18,966	30,112
Net product sales	5,468	4,936	14,934	19,985
Contract research and other	1,576	1,662	5,672	5,624
	102,833	105,979	322,847	325,399
Expenses				
Research and development	127,924	122,043	400,465	364,040
Selling, general, and administrative	17,916	15,658	80,912	44,560
Cost of goods sold	450	372	1,227	1,494
	161,290	138,033	482,604	410,094
Loss from operations	(58,457)	(32,094)	(159,757)	(84,695)
Other income (expense)				
Investment income	715	453	2,750	1,484
Interest expense	(4,061)	(2,234)	(11,827)	(6,660)
	(3,346)	(1,781)	(9,077)	(5,176)
Net loss before income tax expense (benefit)	(61,803)	(33,875)	(168,834)	(89,871)
Income tax expense (benefit)	562		(517)	
Net loss	$ (62,365)	$ (33,875)	$ (168,317)	$ (89,871)
Net loss per share, basic and diluted	$ (0.68)	$ (0.41)	$ (1.87)	$ (1.10)
Weighted average shares outstanding, basic and diluted	91,046	81,658	90,215	81,431

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)
For the nine months ended September 30, 2011 and 2010
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2010	2,187	$ 2	87,258	$ 87	$ 1,575,780	$ (1,045,563)	$ (2,491)	$ 527,815	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			3,000	3	23,819			23,822	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			92		3,409			3,409	
Issuance of restricted Common Stock under Long-Term Incentive Plan			16						
Conversion of Class A Stock to Common Stock	(73)		73						
Stock-based compensation charges					40,768			40,768	
Net loss						(168,317)		(168,317)	$ (168,317)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.5 million							760	760	760
Balance, September 30, 2011	2,109	$ 2	90,419	$ 90	$ 1,643,772	$ (1,213,880)	$ (1,731)	$ 428,253	$ (167,557)
Balance, December 31, 2009	2,248	$ 2	78,861	$ 79	$ 1,356,732	$ (941,095)	$ 1,044	$ 396,762	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			993	1	13,193			13,194	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			111		2,807			2,807	
Issuance of restricted Common Stock under Long-Term Incentive Plan			15						
Conversion of Class A Stock to Common Stock	(63)		63						
Stock-based compensation charges					26,331			26,331	
Net loss						(89,871)		(89,871)	$ (89,871)
Change in net unrealized gain (loss) on marketable securities							(1,219)	(1,219)	(1,219)
Balance, September 30, 2010	2,185	$ 2	80,043	$ 80	$ 1,379,123	$ (1,030,966)	$ (175)	$ 348,064	$ (91,090)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)
(In thousands)

	Nine months ended September 30, 2011	2010
Cash flows from operating activities		
Net loss	$ (168,317)	$ (89,871)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	23,156	13,601
Non-cash compensation expense	40,561	26,331
Other non-cash charges and expenses, net	2,121	2,627
Changes in assets and liabilities		
Decrease (increase) in accounts receivable	14,665	(16,719)
(Increase) decrease in prepaid expenses and other assets	(6,307)	3,446
(Decrease) increase in deferred revenue	(32,498)	172,660
Increase in accounts payable, accrued expenses, and other liabilities	35,254	27,998
Total adjustments	76,952	229,944
Net cash (used in) provided by operating activities	(91,365)	140,073
Cash flows from investing activities		
Purchases of marketable securities	(115,538)	(241,665)
Sales or maturities of marketable securities	324,530	228,483
Capital expenditures	(45,928)	(67,427)
Increase in restricted cash	(685)	(1,800)
Net cash provided by (used in) investing activities	162,379	(82,409)
Cash flows from financing activities		
Proceeds in connection with facility lease obligations		47,544
Payments in connection with facility lease obligations	(468)	(757)
Net proceeds from the issuance of Common Stock	23,989	13,760
Payments in connection with capital lease obligations	(712)	
Net cash provided by financing activities	22,809	60,547
Net increase in cash and cash equivalents	93,823	118,211
Cash and cash equivalents at beginning of period	112,572	207,075
Cash and cash equivalents at end of period	$ 206,395	$ 325,286

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2010 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

Certain reclassifications have been made to the financial statements for the nine months ended September 30, 2010 to conform with the current period's presentation.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, $4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by $0.06 for the nine months ended September 30, 2010.

ARCALYST® net product sales totaled $5.5 million and $4.9 million for the three months ended September 30, 2011 and 2010, respectively, and $14.9 million and $20.0 million for the nine months ended September 30, 2011 and 2010, respectively. ARCALYST® net product sales during the first nine months of 2010 included $15.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at September 30, 2011 or 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled $0.5 million and $0.4 million for the three months ended September 30, 2011 and 2010, respectively, and $1.2 million and $1.5 million for the nine months ended September 30, 2011 and 2010, respectively.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and nine months ended September 30, 2011 and 2010, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2011	2010
Net loss (Numerator)	$ (62,365)	$ (33,875)
Weighted-average shares, in thousands (Denominator)	91,946	81,638
Basic and diluted net loss per share	$ (0.68)	$ (0.41)

	Nine Months Ended September 30,	
	2011	2010
Net loss (Numerator)	$ (168,317)	$ (89,871)
Weighted-average shares, in thousands (Denominator)	90,215	81,433
Basic and diluted net loss per share	$ (1.87)	$ (1.10)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the September 30, 2011 and 2010 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September 30,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	20,395	21,265
Weighted average exercise price	$ 21.24	$ 18.76
Restricted Stock:		
Weighted average number, in thousands	854	511

	Nine months ended September 30,	
	2011	2010
Stock Options:		
Weighted average number, in thousands	21,239	21,317
Weighted average exercise price	$ 20.32	$ 18.67
Restricted Stock:		
Weighted average number, in thousands	848	507

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2011 and December 31, 2010 were $4.9 million and $10.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2010 and December 31, 2009 were $12.0 million and $9.8 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2010 and 2009 were $2.9 million and $2.6 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in facility lease obligations and property, plant, and equipment at September 30, 2010 was $2.6 million of capitalized and deferred interest for the nine months ended September 30, 2010, as the related facilities being leased by the Company were under construction and lease payments on these facilities did not commence until January 2011.

The Company incurred capital lease obligations of $0.7 million during the nine months ended September 30, 2011 in connection with acquisitions of equipment.

Included in marketable securities at September 30, 2011 and December 31, 2010 were $1.1 million and $1.4 million, respectively, of accrued interest income. Included in marketable securities at September 30, 2010 and December 31, 2009 were $1.3 million and $0.6 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at September 30, 2011 and December 31, 2010 consisted of debt securities, as detailed below, and equity securities. The aggregate fair value of the equity securities was $3.1 million and $3.6 million at September 30, 2011 and December 31, 2010, respectively, and the aggregate cost basis was $4.0 million at both September 30, 2011 and December 31, 2010. The Company also held restricted marketable securities at both September 30, 2011 and December 31, 2010, which consisted of debt securities, as detailed below, that collateralize letters of credit and lease obligations.

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at September 30, 2011 and December 31, 2010. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair	Unrealized		
At September 30, 2011	**Cost Basis**	**Value**	**Gains**	**(Losses)**	**Net**
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 2,028	$ 2,033	$ 5		$ 5
U.S. government guaranteed corporate bonds	21,249	21,309	60		60
U.S. government guaranteed collateralized mortgage obligations	986	986			
Municipal bonds	14,722	14,749	27		27
Mortgage-backed securities	26	26			
	39,011	39,103	92		92
Maturities between one and five years					
U.S. government obligations	238,958	239,418	519	$ (59)	460
U.S. government guaranteed corporate bonds	15,415	15,457	42		42
	254,373	254,875	561	(59)	502
Maturities between five and six years					
Mortgage-backed securities	270	123		(147)	(147)
	293,654	294,101	653	(206)	447

At September 30, 2011 (continued)	Amortized Cost Basis	Fair Value	Unrealized Gains	Unrealized (Losses)	Unrealized Net
Restricted					
Maturities within one year					
U.S. government obligations	2,946	2,947	1		1
Maturities between one and three years					
U.S. government obligations	4,261	4,280	19		19
	7,207	7,227	20		20
	$ 300,861	$301,328	$ 673	$ (206)	$ 467
At December 31, 2010					
Unrestricted					
Maturities within one year					
U.S. government obligations	$ 81,635	$ 81,684	$ 54	$ (5)	$ 49
U.S. government guaranteed corporate bonds	48,173	48,531	358		358
U.S. government guaranteed collateralized mortgage obligations	2,027	2,131	104		104
Municipal bonds	1,597	1,603	6		6
Mortgage-backed securities	875	847		(28)	(28)
	136,307	136,796	522	(33)	489
Maturities between one and five years					
U.S. government obligations	352,345	350,683	64	(1,726)	(1,662)
U.S. government guaranteed corporate bonds	15,522	15,477		(45)	(45)
Mortgage-backed securities	110	38		(72)	(72)
	367,977	366,198	64	(1,843)	(1,779)
Maturities between five and seven years					
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year					
U.S. government obligations	2,932	2,921		(11)	(11)
Maturities between one and three years					
U.S. government obligations	4,135	4,118		(17)	(17)
	7,057	7,039		(18)	(18)
	$ 511,625	$510,276	$ 586	$ (1,935)	$(1,349)

At September 30, 2011 and December 31, 2010, marketable securities included an additional unrealized loss of $0.9 million and $0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at September 30, 2011 and December 31, 2010. The debt securities held at September 30, 2011, excluding mortgage-backed securities, mature at various dates through June 2014. The mortgage-backed securities held at September 30, 2011 have various estimated maturity dates through August 2017.

	Less than 12 Months		12 Months or Greater		Total	
At September 30, 2011	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 67,234	$ (59)			$ 67,234	$ (59)
Equity securities	3,075	(969)			3,075	(969)
Mortgage-backed securities			$ 149	$ (147)	149	(147)
	70,309	(1,028)	149	(147)	70,458	(1,175)

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2010	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
U.S. government obligations	$ 340,444	$ (1,731)			$ 340,444	$ (1,731)
U.S. government guaranteed corporate bonds	19,005	(45)			19,005	(45)
Equity securities	3,612	(433)			3,612	(433)
Mortgage-backed securities			$ 1,128	$ (141)	1,128	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Restricted						
U.S. government obligations	6,154	(18)			6,154	(18)
	6,154	(18)			6,154	(18)
	$ 369,215	$ (2,227)	$ 1,128	$ (141)	$ 370,343	$ (2,368)

Realized gains and losses are included as a component of investment income. For the three and nine months ended September 30, 2011 and 2010, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at September 30, 2011 and December 31, 2010, were as follows:

		Fair Value Measurements at Reporting Date Using		
At September 30, 2011	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 241,451		$ 241,451	
U.S. government guaranteed corporate bonds	36,766		36,766	
U.S. government guaranteed collateralized mortgage obligations	986		986	
Municipal bonds	14,749		14,749	
Mortgage-backed securities	149		149	
Equity securities	3,075	$ 3,075		
	297,176	3,075	294,101	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,227		7,227	
	$ 304,403	$ 3,075	$ 301,328	

		Fair Value Measurements at Reporting Date Using		
At December 31, 2010	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Unrestricted				
Available-for-sale marketable securities				
U.S. government obligations	$ 434,367		$ 434,367	
U.S. government guaranteed corporate bonds	64,008		64,008	
U.S. government guaranteed collateralized mortgage obligations	2,131		2,131	
Municipal bonds	1,603		1,603	
Mortgage-backed securities	1,128		1,128	
Equity securities	3,612	$ 3,612		
	506,849	3,612	503,237	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	7,039		7,039	
	$ 513,888	$ 3,612	$ 510,276	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the nine months ended September 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover a portion of the security's carrying value. As a result, the Company recognized a $0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three and nine months ended September 30, 2011, and the three months ended September 30, 2010, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

The Company holds one Level 3 marketable security, which had no fair value at September 30, 2011 and December 31, 2010. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the security's lack of liquidity. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and nine months ended September 30, 2011 and 2010. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2011 and 2010.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Inventory

Inventories as of September 30, 2011 and December 31, 2010 consist of the following:

	September 30, 2011	December 31, 2010
Raw materials	$ 223	$ 592
Work in process	7,728	699
Finished goods	83	132
	$ 8,034	$ 1,423

At September 30, 2011, $1.0 million of inventories were included in prepaid expenses and other current assets and $7.0 million of inventories were included in other assets. At December 31, 2010, inventories were included in prepaid expenses and other current assets.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2011 and December 31, 2010 consist of the following:

	September 30, 2011	December 31, 2010
Accounts payable	$ 17,309	$ 15,589
Accrued payroll and related costs	37,616	12,025
Accrued clinical trial expense	10,018	9,727
Accrued property, plant, and equipment costs	2,333	7,622
Other accrued expenses and liabilities	8,208	6,441
Payable to Bayer HealthCare LLC	3,406	2,254
	$ 78,890	$ 53,658

8. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and nine months ended September 30, 2011 and 2010, the components of comprehensive loss are:

	Three months ended September 30,	
	2011	2010
Net loss	$ (62,365)	$ (33,875)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.6 million in 2011	(827)	131
Total comprehensive loss	$ (63,192)	$ (33,744)

	Nine months ended September 30,	
	2011	2010
Net loss	$ (168,317)	$ (89,871)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.5 million in 2011	760	(1,219)
Total comprehensive loss	$ (167,557)	$ (91,090)

9. Income Taxes

For the three and nine months ended September 30, 2011 and 2010, the Company incurred net losses for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three and nine months ended September 30, 2011, the Company recognized income tax expense of $0.6 million and an income tax benefit of $0.5 million, respectively, in connection with the net tax effect of the change in the Company's unrealized gain/(loss) on "available-for-sale" marketable securities, which is included in other comprehensive loss. For the three and nine months ended September 30, 2010, no provision or benefit for income taxes was recorded.

10. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current ordinary course legal proceedings to have a material adverse effect on the Company's business or financial condition. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

As previously reported, on November 19, 2010, the Company filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to the Company's VEGF Trap (aflibercept) infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon the Company's submission to the FDA of a Biologics License Application (BLA) for EYLEA™ (aflibercept injection) for the treatment of age-related macular degeneration (wet AMD), the Company filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, the Company and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, the Company voluntarily dismissed its original complaint in favor of proceeding with its second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that the Company is entitled to the declaratory relief being sought by the Company, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that the Company is entitled to the declaratory relief being sought by the Company, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, the Company replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of the Company's prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. The Company believes Genentech's counterclaims are without merit and intends to continue to defend against them vigorously. As this litigation is at an early stage, at this time the Company is not able to predict the probability of the outcome or an estimate of loss, if any, related to this matter.

The Company has initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy, and may initiate other actions in other countries outside the U.S.

11. Subsequent Event – Offering of Senior Convertible Notes

On October 17, 2011, the Company announced an offering of $400 million aggregate principal amount of 1.875% convertible senior notes (the "Notes") due October 1, 2016. The offering closed on October 21, 2011. The initial purchaser of the Notes has a 13-day option to purchase up to an additional $60 million aggregate principal amount of Notes on the same terms and conditions.

The Notes will pay interest semi-annually on April 1 and October 1 at an annual rate of 1.875%, and will mature on October 1, 2016, unless earlier converted or repurchased. The Notes will be convertible, subject to certain conditions, into cash, shares of the Company's Common Stock, or a combination of cash and shares of Common Stock, at the Company's option. The initial conversion rate for the Notes will be 11.9021 shares of Common Stock (subject to adjustment in certain circumstances) per $1,000 principal amount of the Notes, which is equal to an initial conversion price of approximately $84.02 per share.

In connection with the offering of the Notes, the Company entered into convertible note hedge and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of the Company's Common Stock that initially underlie the Notes, and are intended to reduce the dilutive impact of the conversion feature of the Notes. The warrant transactions will have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of the Company's Common Stock, at the Company's option.

The net proceeds from the Notes offering were approximately $391.3 million after deducting the initial purchaser's discount and estimated offering expenses (and will be approximately $450.1 million if the initial purchaser exercises in full its option to purchase additional Notes). In addition, the cost of the initial convertible note hedge, after taking into account the proceeds received by the Company from the warrant transactions, was $23.7 million. If the initial purchaser exercises its option to purchase additional Notes, the Company may use net proceeds from the sale of the additional Notes to enter into additional convertible note hedge and warrant transactions.

12. Recently Issued Accounting Standards

Multiple-deliverable revenue arrangements

During the first quarter of 2011 the Company adopted amended authoritative guidance issued by the Financial Accounting Standards Board ("FASB") on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-deliverable revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. The Company is applying this amended guidance prospectively for new or materially modified arrangements, of which there were none during the nine months ended September 30, 2011. The adoption of this guidance did not have a material impact on the Company's financial statements.

Milestone method of revenue recognition

During the first quarter of 2011, the Company adopted amended authoritative guidance issued by the FASB codifying the milestone method of revenue recognition as an acceptable revenue recognition model when a milestone is deemed to be substantive. Since the Company has historically accounted for milestones under the milestone method, the adoption of this guidance did not have a material impact on the Company's financial statements.

In accordance with the Company's accounting policy for recognition of revenue in connection with collaboration agreements, as previously disclosed in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company earns substantive performance milestone payments in connection with its collaboration agreements to develop and commercialize product candidates with Sanofi and Bayer HealthCare. Descriptions of these collaboration agreements, including various financial terms and conditions, were provided in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Under the Company's collaboration agreement with Sanofi to jointly develop and commercialize ZALTRAP® (aflibercept, also known as VEGF Trap), the Company may receive up to $400 million in substantive milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight ZALTRAP® oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five ZALTRAP® oncology indications in Japan. Under the Company's global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies, for each drug candidate identified under the collaboration's Discovery and Preclinical Development Agreement, Sanofi has the option to license rights to the candidate under the collaboration's License and Collaboration Agreement and co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10 million substantive milestone payment to the Company. Under the Company's license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the U.S., EYLEA™, the Company is eligible to receive up to $50 million in future substantive milestone payments related to marketing approvals of EYLEA™ in major market countries outside the U.S.

Fees paid to the federal government by pharmaceutical manufacturers

In December 2010, the FASB provided authoritative guidance on how pharmaceutical manufacturers should recognize and classify in their income statement annual fees mandated by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act. This guidance became effective for calendar years beginning after December 31, 2010. The adoption of this guidance did not have an impact on the Company's financial statements as the fee does not currently apply to the Company. The Company's marketed product, ARCALYST® for the treatment of CAPS, has been approved as an orphan drug and orphan drugs are not subject to this annual fee.

Presentation of comprehensive income

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on the Company's financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among other things, the nature, timing, and possible success of and therapeutic applications for our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be canceled or terminated without any product success, and risks associated with third-party intellectual property and pending or future litigation relating thereto. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, manufactures, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available by prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have 11 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based, late-stage (Phase 3) programs are:

- EYLEA™ (aflibercept injection), also known as VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of serious eye diseases;
- ZALTRAP® (aflibercept), also known as VEGF Trap, which is being developed in oncology in collaboration with Sanofi; and
- ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment.

Our antibody-based clinical programs include the following fully human monoclonal antibodies:

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis;
- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and eosinophilic asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold);
- REGN728, an antibody in clinical development against an undisclosed target; and
- REGN846, an antibody against an undisclosed target, which is being developed in atopic dermatitis.

With the exception of REGN846, which we are developing independently, all of these antibodies are being developed in collaboration with Sanofi.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*®. Under the terms of our antibody collaboration with Sanofi, which was expanded during 2009, we plan to advance a total of approximately 30 candidates into clinical development over the life of the agreement. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® – CAPS

Net product sales of ARCALYST® (rilonacept) in the third quarter of 2011 were $5.5 million, compared to $4.9 million during the same quarter of 2010. ARCALYST® net product sales for the nine months ended September 30, 2011 and 2010, respectively, totaled $14.9 million and $20.0 million. ARCALYST® net product sales during the first nine months of 2010 included $15.2 million of net product sales made during this period and $4.8 million of previously deferred net product sales, as described below under "Results of Operations."

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST® is available by prescription in the U.S. for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. EYLEA™ (aflibercept injection) also known as VEGF Trap-Eye – Ophthalmologic Diseases

EYLEA™ (aflibercept injection) is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF) proteins that are involved in the abnormal growth of new blood vessels. We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating EYLEA™ in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared EYLEA™ and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-VEGF agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated EYLEA™ doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (following three initial monthly doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with EYLEA™ who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis®. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of EYLEA™, including EYLEA™ dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month.

A generally favorable safety profile was observed for both EYLEA™ and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in February 2011 for marketing approval of EYLEA™ in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA unanimously recommended that the FDA approve our BLA. Also in June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA™ in wet AMD in the European Union and Japan. In August 2011, we announced that we received notification from the FDA that the agency had extended its target date to complete the priority review of the EYLEA™ BLA to November 18, 2011, which is a three month extension from the original Prescription Drug User Fee Act (PDUFA) action date. The extension is a result of the agency classifying our responses to questions regarding the chemistry, manufacturing, and controls (CMC) section of the BLA as a major amendment to the BLA. The new action date provides the agency additional time to review the information submitted.

EYLEA™ is also in Phase 3 clinical studies for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either EYLEA™ at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment as measured by the ETDRS eye chart. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

In December 2010, we and Bayer HealthCare announced that in the COPERNICUS study, EYLEA™ demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In the study, EYLEA™ was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the EYLEA™ group were uncommon (3.5%), consisting of individual reports of corneal abrasion, endophalmitis, retinal vein occlusion, and reduced visual acuity, and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with EYLEA™ and two (2.7%) in the 73 patients treated with sham injections.

In April 2011, we and Bayer HealthCare announced that in the GALILEO study, EYLEA™ also demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In this trial, 60.2% of patients receiving 2.0 mg of EYLEA™ monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). Patients receiving 2.0 mg of EYLEA™ monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

As in the COPERNICUS trial, EYLEA™ was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the EYLEA™ group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the EYLEA™ arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduced visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

Based on these positive results, we intend to submit a regulatory application for marketing approval for EYLEA™ in CRVO in the U.S. by the end of 2011, and Bayer HealthCare plans to submit regulatory applications in this indication in Europe in 2012.

In the second quarter of 2011, we and Bayer HealthCare initiated Phase 3 studies to evaluate the safety and efficacy of EYLEA™ in DME. These clinical trials have three study arms. In the first arm, patients will be treated every month with 2.0 mg of EYLEA™. In the second arm, patients will be treated with 2.0 mg of EYLEA™ every two months after an initial phase of monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint of the study is mean change in visual acuity from baseline as measured by the ETDRS eye chart. All patients will be followed for three years. We are conducting one of these studies, called VISTA-DME (VEGF Trap-Eye: Investigation of Safety, Treatment effect, and Anatomic outcomes in DME), with study centers in the U.S. and other countries. Bayer HealthCare is conducting the second study, named VIVID-DME (VEGF Trap-Eye In Vision Impairment Due to DME), with study centers in Europe, Japan, and Australia.

In the first quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of EYLEA™ in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the U.S. of EYLEA™. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA™ through an integrated global plan. Bayer HealthCare will market EYLEA™ outside the U.S., where the companies will share equally in profits from any future sales of EYLEA™. Commencing on the first commercial sale of EYLEA™ in a major market country outside the U.S., we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. Within the U.S., we retain exclusive commercialization rights to EYLEA™ and are entitled to all profits from any such sales. We have received $60 million in development milestone payments and can earn up to $50 million in future milestone payments related to marketing approvals of EYLEA™ in major market countries outside the U.S. We can also earn up to $135 million in sales milestone payments if total annual sales of EYLEA™ outside the U.S. achieve certain specified levels starting at $200 million.

2. ZALTRAP® (aflibercept) also known as VEGF Trap – Oncology

ZALTRAP® (aflibercept) is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and PlGF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

ZALTRAP® is being developed globally in cancer indications in collaboration with Sanofi. In April 2011, we and Sanofi announced that the Phase 3 VELOUR trial evaluating ZALTRAP® in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in previously treated metastatic colorectal cancer (mCRC) patients. The VELOUR data were presented in June 2011 at the European Society of Medical Oncology World Congress on Gastrointestinal Cancer. In this study, the addition of ZALTRAP® to the FOLFIRI chemotherapy regimen significantly improved both overall survival (HR=0.817; p=0.0032) and progression-free survival (HR=0.758; p=0.00007) compared to FOLFIRI plus placebo. A similar effect was seen with ZALTRAP® therapy whether or not patients had received prior bevacizumab therapy.

In the VELOUR study, grade 3 or 4 adverse events that occurred with a more than two percent greater incidence in the ZALTRAP® arm than in the placebo arm included diarrhea, asthenia/fatigue, stomatitis/ulceration, infections, hypertension, GI/abdominal pains, neutropenia, neutropenic complications and proteinuria. Deaths on study treatment due to adverse events occurred in 2.4 percent of patients in the ZALTRAP® arm and in 1.0 percent of patients in the placebo arm.

Based upon these positive findings, we and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP® for the treatment of previously-treated mCRC patients to the FDA and the European Medicines Agency (EMA) by the end of 2011.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP® as a first-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. The VENICE trial is being monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the trial and may recommend changes in study design or study discontinuation. In July 2011, the study's IDMC met for a scheduled interim analysis and recommended that the trial continue to completion. A final analysis will be conducted when a pre-specified number of events have occurred in this trial, which is anticipated in the first half of 2012.

In addition, a randomized Phase 2 study (AFFIRM) of ZALTRAP® in first-line mCRC in combination with FOLFOX [folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin] is fully enrolled. Initial data from this study are anticipated by the end of 2011.

ZALTRAP® Collaboration with Sanofi

We and Sanofi globally collaborate on the development and commercialization of ZALTRAP®. Under the terms of our September 2003 collaboration agreement, as amended, we and Sanofi will share co-promotion rights and profits on sales, if any, of ZALTRAP® outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of ZALTRAP®, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million related to the receipt of marketing approvals for up to eight ZALTRAP® oncology and other indications in the U.S. or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the ZALTRAP® collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by Sanofi. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi out of our share of ZALTRAP® profits for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAP® profits in the quarter unless we elect to reimburse Sanofi at a faster rate.

3. ARCALYST® (rilonacept) – Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break-up of urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We conducted a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program consisted of three studies: PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations).

In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period.

In addition, all secondary endpoints of the study were positive ($p<0.001$ vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88%. Treatment with ARCALYST® also reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65%.

In February 2011, we reported the results of PRE-SURGE 2 and RE-SURGE. In the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, which was identical to PRE-SURGE 1 in design and analysis, 248 patients were randomized. ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). Among secondary endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 82%. In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 63%.

We also announced that in the RE-SURGE study, which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. In the overall gout program, the most frequently reported adverse events were injection site reaction and headache.

In the RE-SURGE study, ARCALYST® also met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Based on the results of the three Phase 3 studies, we submitted a supplemental BLA for U.S. regulatory approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In addition, we plan to initiate a long-term safety study in this setting, known as UPSURGE (Understanding long-term safety in a Preventative Study against URate-lowering drug-induced Gout Exacerbations). We own worldwide rights to ARCALYST®.

4. Sarilumab (REGN88; IL-6R Antibody) for inflammatory diseases

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, Actemra® (tocilizumab), a registered trademark of Chugai Seiyaku Kabushiki Kaisha, has been approved for the treatment of rheumatoid arthritis.

Sarilumab is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology. In July 2011, we and Sanofi announced that in the Phase 2b stage of the MOBILITY trial in rheumatoid arthritis, patients treated with sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA compared to patients treated with MTX alone. The Phase 2b stage of the MOBILITY study was a 306-patient, dose-ranging, multi-national, randomized, multi-arm, double-blind, placebo-controlled study, that compared five different dose regimens of sarilumab in combination with MTX to placebo plus MTX. The primary endpoint of the study was the proportion of patients achieving at least a 20% improvement in RA symptoms (ACR20) after 12 weeks.

In the Phase 2b stage of the MOBILITY trial, there was a dose response observed in patients receiving sarilumab in combination with MTX. An ACR20 response after 12 weeks was seen in 49.0% of patients receiving the lowest sarilumab dose regimen and 72.0% of patients receiving the highest dose regimen compared to 46.2% of patients receiving placebo and MTX ($p=0.02$, corrected for multiplicity, for the highest sarilumab dose regimen). The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities. The types and frequencies of adverse events were consistent with those previously reported with IL-6 inhibition. The incidence of serious adverse events among the five sarilumab treatment groups and the placebo group was comparable.

Sarilumab also demonstrated significant benefit compared to placebo in secondary endpoints, including ACR 50, ACR 70, and Disease Activity Score (DAS) 28 scores, additional measures of clinical activity used in RA trials.

In July 2011, we and Sanofi announced that in the phase 2b ALIGN trial in ankylosing spondylitis, sarilumab did not demonstrate significant improvements in the signs and symptoms of active AS compared to placebo in patients who had inadequate response to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Sarilumab was generally well tolerated. The most common adverse events reported more frequently in active treatment arms included infections and neutropenia.

During the third quarter of 2011, we and Sanofi initiated the Phase 3 stage of the Phase 2/3 MOBILITY study.

5. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune®* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to lower LDL cholesterol.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. In these early trials, REGN727 was generally safe and well tolerated with no trend in drug-related adverse events and no evidence of hepato- or myo-toxicity. Injection site reactions were minimal.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported.

During 2011, three Phase 2 studies with subcutaneous regimens of REGN727 have been initiated: (1) a randomized, double-blind, multi-dose, placebo controlled, 75-patient trial in patients with heterozygous familial hypercholesterolemia (heFH), (2) a randomized, double-blind, multi-dose, placebo controlled, 90-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia, and (3) a randomized, double-blind, multi-dose, placebo controlled, 180-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia and on stable doses of atorvastatin. The primary endpoint of each Phase 2 study is the change in LDL cholesterol from baseline compared to placebo over the study period. Initial data from these Phase 2 studies will be available by the end of 2011 and the first half of 2012.

REGN727 is being developed in collaboration with Sanofi.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune*® technology that is designed to bind to IL-4R. REGN668 is in a Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma. REGN668 is being developed in collaboration with Sanofi.

7. REGN421 (Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune*® technology, and is in Phase 1 clinical development. REGN421 is being developed in collaboration with Sanofi.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a Phase 1 study in an oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is a fully human monoclonal antibody generated using our *VelocImmune*® technology, which is being developed for cancer indications. REGN910 is being developed in collaboration with Sanofi.

9. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune*® technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF.

In May 2010, we announced positive results from an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. The FDA Arthritis Advisory Committee meeting scheduled for September 13, 2011 to discuss possible safety issues related to anti-NGF compounds has been postponed. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with Sanofi.

10. REGN728

In the fourth quarter of 2010, clinical trials began with REGN728, a fully human monoclonal antibody generated using our *VelocImmune®* technology, against an undisclosed target. REGN728 is being developed in collaboration with Sanofi.

11. REGN846

REGN846 is a fully human monoclonal antibody generated using our *VelocImmune®* technology, against an undisclosed target, and is being evaluated in a Phase 2a study in patients with atopic dermatitis. In July 2011, Sanofi elected not to continue co-development of REGN846, and Regeneron now has sole global rights to REGN846. Under the terms of our agreement, Sanofi remains obligated to fund REGN846 clinical costs through conclusion of a planned proof-of-concept trial and is entitled to receive a mid-single digit royalty on any future sales of REGN846.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as ZALTRAP® and EYLEA™, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite™

VelociSuite™ consists of *VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®*. The *VelocImmune®* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune®* was generated by exploiting our *VelociGene®* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune®* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune®* and our entire *VelociSuite™* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune®* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse®* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

Sanofi. In November 2007, we and Sanofi entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of $85.0 million from Sanofi. Pursuant to the collaboration, Sanofi is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified through discovery research under the discovery agreement, Sanofi has the option to license rights to the candidate under the license agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

Sanofi will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the U.S. The parties will share profits outside the U.S. on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and will share losses outside the U.S. at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the U.S. exceed $1.0 billion on a rolling 12-month basis.

In November 2009, we and Sanofi amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance a total of approximately 30 new antibody product candidates into clinical development from 2010 through 2017.

Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for Sanofi to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, Sanofi is also obligated to fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, Sanofi funded $137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and $160 million, or $22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement.

From the collaboration's inception in November 2007 through September 30, 2011, Sanofi has funded a total of $435.3 million of our costs under the discovery agreement and a total of $364.9 million of our development costs under the license agreement, or a total of $800.2 million in funding for our antibody research and development activities during this period.

In August 2008, we entered into an agreement with Sanofi to use our *VelociGene*® platform to supply Sanofi with genetically modified mammalian models of gene function and disease. Under this agreement, Sanofi is required to pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by Sanofi. Sanofi will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune*® technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. While our royalties under this agreement could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. We are unable to predict whether canakinumab will be approved for gout or any other indication in addition to CAPS, or whether, even if approved, canakinumab for such indication(s) will be successfully commercialized. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, $24.6 million has been received or is receivable from the grant's inception as of September 30, 2011 and we are entitled to receive an additional $0.7 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General:

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2011, we had a cumulative loss of $1.2 billion, principally related to our research and development activities. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. We submitted a BLA to the FDA in February 2011 for marketing approval of EYLEA™ in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. In August 2011, Regeneron announced that we received notification from the FDA that the agency had extended its target date to complete the priority review of our BLA for EYLEA™ to November 18, 2011, which is a three month extension from the original PDUFA action date. The extension is a result of the agency classifying our responses to questions regarding the CMC section of the BLA as a major amendment to the BLA. The new action date provides the agency additional time to review the information submitted. In June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA™ in wet AMD in the European Union and in Japan. We intend to submit a BLA to the FDA by the end of 2011 for marketing approval of EYLEA™ in CRVO in the U.S., and Bayer HealthCare is planning to submit regulatory applications for marketing approval of EYLEA™ in CRVO in Europe in 2012. We have also submitted a supplemental BLA for marketing approval in the U.S. of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We and Sanofi plan to submit regulatory applications for marketing approval of ZALTRAP® for the treatment of patients with previously treated mCRC to the FDA and the EMA by the end of 2011.

We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product(s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and development efforts, the progress of our efforts to commercialize our late-stage product candidates, the timing of certain expenses, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when our late-stage product candidates, including EYLEA™ in wet AMD, will receive regulatory approval or, if such approval is received, whether we will be able to successfully commercialize such product(s), or if we do commercialize such product(s), whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2011 to date were, and plans for the next 12 months are, as follows:

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
EYLEA™	• Submitted a BLA to the U.S. FDA for the treatment of wet AMD • FDA accepted BLA for wet AMD and granted our request for Priority Review • FDA Advisory Committee unanimously recommended FDA approval of BLA for the treatment of wet AMD • FDA extended the target date for a decision on the BLA for the treatment of wet AMD to November 18, 2011 • Bayer HealthCare submitted regulatory applications for marketing approval for EYLEA™ for the treatment of wet AMD in the European Union and Japan • Reported positive six-month results in the Phase 3 GALILEO trial in CRVO • Reported positive one-year data from the Phase 3 COPERICUS trial in CRVO • Initiated Phase 3 trials in DME in the U.S. and outside the U.S. • Bayer HealthCare initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia	• Report two-year data from VIEW 1 and VIEW 2 trials in wet AMD by the end of 2011 • Report one-year data from GALILEO trial in CRVO by the end of 2011 • Submit a BLA to the FDA for the treatment of CRVO by the end of 2011 • Target date for FDA decision on BLA for the treatment of wet AMD is November 18, 2011
ZALTRAP®	• Presented positive results from the Phase 3 VELOUR trial in previously treated mCRC patients • IDMC reviewed interim results for the Phase 3 VENICE trial in prostate cancer and recommended study continue to completion • Reported results for the VITAL trial in non-small cell lung cancer. ZALTRAP® did not meet primary study endpoint.	• Submit a BLA to the FDA for the treatment of mCRC by the end of 2011 • Report initial results in the Phase 2 AFFIRM trial in first-line mCRC by the end of 2011 • Report final results in the Phase 3 VENICE trial in prostate cancer in the first half of 2012

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
ARCALYST®	• Reported positive results from two Phase 3 studies for the prevention of gout flares (PRE-SURGE 2 and RE-SURGE) • Submitted a supplemental BLA for U.S. regulatory approval for the prevention of gout flares	• Initiate a long-term safety study for the prevention of gout flares (UPSURGE)
Sarilumab (IL-6R Antibody)	• Reported positive Phase 2b data from the MOBILITY trial in rheumatoid arthritis • Reported that the Phase 2b trial in ankylosing spondylitis did not meet its primary endpoint • Initiated the Phase 3 stage of the Phase 2/3 MOBILITY trial	
REGN727 (PCSK9 Antibody)	• Initiated Phase 2 studies for LDL cholesterol reduction	• Report initial data from the Phase 2 program for LDL cholesterol reduction • Initiate Phase 3 program for LDL cholesterol reduction
REGN668 (IL-4R Antibody)	• Initiated Phase 1b study in atopic dermatitis and Phase 2 proof of concept study in eosinophilic asthma	• Initiate Phase 2 program in atopic dermatitis
REGN421 (Dll4 Antibody)	• Continued patient enrollment in Phase 1 program	• Initiate a Phase 1b program in advanced malignancies
REGN910 (ANG2 Antibody)	• Continued patient enrollment in Phase 1 program	
REGN475 (NGF Antibody)	• On clinical hold	
REGN728 (target not disclosed)	• Continued patient enrollment in Phase 1 program	
REGN846 (target not disclosed)	• Continued patient enrollment in Phase 1 program • Sanofi elected not to co-develop REGN846 • Initiated Phase 2a program in atopic dermatitis	

Results of Operations

Three Months Ended September 30, 2011 and 2010

Net Loss

Regeneron reported a net loss of $62.4 million, or $0.68 per share (basic and diluted), for the third quarter of 2011, compared to a net loss of $33.9 million, or $0.41 per share (basic and diluted), for the third quarter of 2010. The increase in our net loss in 2011 was principally due to higher selling, general, and administrative expenses, partly in connection with preparing to commercialize EYLEA™ in wet AMD, and higher research and development expenses.

Revenues

Revenues for the three months ended September 30, 2011 and 2010 consist of the following:

(In millions)	2011	2010
Collaboration revenue		
Sanofi	$ 79.8	$ 75.6
Bayer HealthCare	10.1	13.8
Total collaboration revenue	89.9	89.4
Technology licensing revenue	5.9	10.0
Net product sales	5.5	4.9
Contract research and other revenue	1.5	1.7
Total revenue	$ 102.8	$ 106.0

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP® collaboration and $85.0 million related to the antibody collaboration.

Sanofi Collaboration Revenue	Three months ended September 30,	
(In millions)	2011	2010
ZALTRAP®		
Regeneron expense reimbursement	$ 2.9	$ 3.9
Regeneron share of ZALTRAP® commercialization expenses	(2.7)	
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total ZALTRAP®	2.7	6.4
Antibody:		
Regeneron expense reimbursement	74.7	66.8
Recognition of deferred revenue related to up-front and other payments	2.0	2.0
Recognition of revenue related to *VelocImmune®* agreement	0.4	0.4
Total antibody	77.1	69.2
Total Sanofi collaboration revenue	$ 79.8	$ 75.6

Sanofi's reimbursement of our ZALTRAP® expenses decreased in the third quarter of 2011 compared to the same quarter in 2010, primarily due to a decrease in internal research activities. Effective in the second quarter of 2011, we and Sanofi began equally sharing pre-launch commercialization expenses related to ZALTRAP® in accordance with the companies' collaboration agreement. Our share of these expenses was $2.7 million in the third quarter of 2011, which reduced our Sanofi collaboration revenue. In connection with recognition of deferred revenue related to ZALTRAP®, as of September 30, 2011, $25.1 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

In the third quarter of 2011, Sanofi's reimbursement of our antibody expenses consisted of $39.8 million under the discovery agreement and $34.9 million of development costs under the license agreement, compared to $36.9 million and $29.9 million, respectively, in the third quarter of 2010. The higher reimbursement amounts in the third quarter of 2011, compared to the same quarter in 2010, were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue related to Sanofi's $85.0 million up-front payment and other payments was $2.0 million for both three months ended September 30, 2011 and 2010. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $26.4 million was received or receivable as of September 30, 2011. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the performance period applicable to recognition of the original $85.0 million up-front payment. As of September 30, 2011, $76.7 million of the Sanofi up-front and other payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with Sanofi. For both three month periods ended September 30, 2011 and 2010, we recognized $0.4 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron's global EYLEA™ development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Three months ended September 30,**	
(In millions)	**2011**	**2010**
Cost-sharing of Regeneron EYLEA™ development expenses	$ 7.6	$ 11.3
Recognition of deferred revenue related to up-front and other milestone payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	$ 10.1	$ 13.8

Cost-sharing of our global EYLEA™ development expenses with Bayer HealthCare decreased in the third quarter of 2011 compared to the same period in 2010. In the third quarter of 2011, we incurred lower clinical development costs primarily in connection with our Phase 3 VIEW 1 trial in wet AMD. In connection with the recognition of deferred revenue related to the $75.0 million up-front payment and $20.0 million milestone payment received in August 2007, as of September 30, 2011, $39.5 million of these payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In connection with our *VelocImmune®* license agreement with AstraZeneca, which terminated effective as of February 2011, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably through February 2011. In the third quarter of 2011, we recognized $5.9 million of technology licensing revenue related to the Astellas agreement. In the third quarter of 2010, we recognized a total of $10.0 million of technology licensing revenue related to both the Astellas and AstraZeneca agreements. As of September 30, 2011, $157.6 million of technology licensing payments received from Astellas was deferred and will be recognized as revenue in future periods.

Net Product Sales

For the three months ended September 30, 2011 and 2010, we recognized as revenue $5.5 million and $4.9 million, respectively, of ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended September 30, 2011 and 2010 included $1.0 million and $1.2 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $161.3 million in the third quarter of 2011 from $138.1 million in the third quarter of 2010. Our average headcount in the third quarter of 2011 increased to 1,646 from 1,317 in the same quarter of 2010, principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi, and 2011 activities in connection with preparing to commercialize EYLEA™ in wet AMD.

Operating expenses in the third quarter of 2011 and 2010 included a total of $13.4 million and $8.8 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended September 30, 2011		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 119.8	$ 8.1	$ 127.9
Selling, general, and administrative	27.6	5.3	32.9
Cost of goods sold	0.5		0.5
Total operating expenses	$ 147.9	$ 13.4	$ 161.3

	For the three months ended September 30, 2010		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 116.7	$ 5.3	$ 122.0
Selling, general, and administrative	12.2	3.5	15.7
Cost of goods sold	0.4		0.4
Total operating expenses	$ 129.3	$ 8.8	$ 138.1

The increase in total Non-cash Compensation Expense in the third quarter of 2011 was primarily attributable to (i) the recognition of higher expense in the third quarter of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to $127.9 million in the third quarter of 2011 from $122.0 million in the same period of 2010. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2011 and 2010:

Research and Development Expenses	For the three months ended September 30,		Increase
(In millions)	2011	2010	(Decrease)
Payroll and benefits (1)	$ 42.2	$ 34.7	$ 7.5
Clinical trial expenses	18.0	23.1	(5.1)
Clinical manufacturing costs (2)	28.4	25.1	3.3
Research and other development costs	13.8	13.8	-
Occupancy and other operating costs	16.3	13.5	2.8
Cost-sharing of Bayer HealthCare EYLEA™ development expenses (3)	9.2	11.8	(2.6)
Total research and development expenses	$ 127.9	$ 122.0	$ 5.9

(1) Includes $7.1 million and $4.6 million of Non-cash Compensation Expense for the three months ended September 30, 2011 and 2010, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $1.0 million and $0.7 million of Non-cash Compensation Expense for the three months ended September 30, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs global EYLEA™ development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's global EYLEA™ development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated global EYLEA™ development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its global EYLEA™ development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, our VIEW 1 trial for EYLEA™ in wet AMD, and our clinical development program for REGN475, which is currently on clinical hold. These decreases were partly offset by higher expenses related to our Phase 3 trial for EYLEA™ in DME. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing supplies of antibody candidates. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and expanded leased facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's global EYLEA™ development expenses decreased primarily due to lower costs in connection with Bayer HealthCare's VIEW 2 trial in wet AMD, partly offset by higher costs in connection with Bayer HealthCare's Phase 3 trial in DME.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA™ development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the three months ended September 30,		Increase
(In millions)	2011	2010	(Decrease)
ARCALYST®	$ 13.7	$ 16.5	$ (2.8)
EYLEA™	31.7	33.2	(1.5)
ZALTRAP®	3.2	2.8	0.4
Sarilumab	3.9	6.0	(2.1)
REGN727	7.6	5.9	1.7
Other antibody candidates in clinical development	19.7	12.5	7.2
Other research programs & unallocated costs	48.1	45.1	3.0
Total research and development expenses	$ 127.9	$ 122.0	$ 5.9

Drug development and approval in the U.S. is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3b and 4 studies. Phase 3b studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, ZALTRAP®, and EYLEA™ in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors" under "Risks Related to the Development and Approval of Our Product Candidates," "Risks Related to Commercialization of Products," and "Regulatory and Litigation Risks." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $32.9 million in the third quarter of 2011 from $15.7 million in the same period of 2010 due primarily to increases in compensation expense and recruitment costs principally in connection with higher headcount in the third quarter of 2011, higher commercialization-related costs, primarily in connection with preparing to commercialize EYLEA™ in wet AMD, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons previously described above.

Cost of Goods Sold

Cost of goods sold in the third quarter of 2011 and 2010 was $0.5 million and $0.4 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $0.7 million in the third quarter of 2011 from $0.5 million in the same period of 2010, due primarily to higher average balances of cash and marketable securities.

Interest expense increased to $4.1 million in the third quarter of 2011 from $2.2 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Nine Months Ended September 30, 2011 and 2010

Net Loss

Regeneron reported a net loss of $168.3 million, or $1.87 per share (basic and diluted), for the first nine months of 2011, compared to a net loss of $89.9 million, or $1.10 per share (basic and diluted) for the first nine months of 2010. The increase in our net loss in 2011 was principally due to higher research and development expenses and higher selling, general, and administrative expenses.

Revenues

Revenues for the nine months ended September 30, 2011 and 2010 consist of the following:

(In millions)	**2011**	**2010**
Collaboration revenue		
Sanofi	$ 249.6	$ 229.2
Bayer HealthCare	33.7	40.5
Total collaboration revenue	283.3	269.7
Technology licensing revenue	18.9	30.1
Net product sales	14.9	20.0
Contract research and other revenue	5.7	5.6
Total revenue	$ 322.8	$ 325.4

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP® collaboration and $85.0 million related to the antibody collaboration.

Sanofi Collaboration Revenue	**Nine months ended September 30,**	
(In millions)	**2011**	**2010**
ZALTRAP®		
Regeneron expense reimbursement	$ 14.4	$ 12.6
Regeneron share of ZALTRAP® commercialization expenses	(4.0)	
Recognition of deferred revenue related to up-front payments	7.4	7.4
Total ZALTRAP®	17.8	20.0
Antibody:		
Regeneron expense reimbursement	224.5	202.7
Recognition of deferred revenue related to up-front and other payments	6.1	5.3
Recognition of revenue related to *VelocImmune*® agreement	1.2	1.2
Total antibody	231.8	209.2
Total Sanofi collaboration revenue	$ 249.6	$ 229.2

Sanofi's reimbursement of our ZALTRAP® expenses increased in the first nine months of 2011 compared to the same period in 2010, primarily due to higher costs related to manufacturing ZALTRAP® clinical supplies. Effective in the second quarter of 2011, we and Sanofi began equally sharing pre-launch commercialization expenses related to ZALTRAP® in accordance with the companies' collaboration agreement. Our share of these expenses was $4.0 million in the first nine months of 2011, which reduced our Sanofi collaboration revenue.

In the first nine months of 2011, Sanofi's reimbursement of our antibody expenses consisted of $122.6 million under the discovery agreement and $101.9 million of development costs under the license agreement, compared to $100.3 million and $102.4 million, respectively, in the first nine months of 2010. The higher reimbursement amount under the discovery agreement in the first nine months of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities. The slightly lower reimbursement of development costs in the first nine months of 2011, compared to the same period in 2010, was primarily due to a decrease in development activities related to REGN475, which is currently on clinical hold, offset by increases in development activities for other antibody candidates.

Recognition of deferred revenue related to Sanofi's $85.0 million up-front payment and other payments increased in the first nine months of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, Sanofi is funding up to $30 million of agreed-upon costs to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $26.4 million was received or receivable as of September 30, 2011. Revenue related to such funding from Sanofi is deferred and recognized as collaboration revenue prospectively over the performance period applicable to recognition of the original $85.0 million up-front payment.

In August 2008, we entered into a separate *VelociGene*® agreement with Sanofi. For both nine month periods ended September 30, 2011 and 2010, we recognized $1.2 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron's global EYLEA™ development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment received in October 2006 and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	**Nine months ended September 30,**	
(In millions)	**2011**	**2010**
Cost-sharing of Regeneron EYLEA™ development expenses	$ 26.3	$ 33.1
Recognition of deferred revenue related to up-front and other milestone payments	7.4	7.4
Total Bayer HealthCare collaboration revenue	$ 33.7	$ 40.5

Cost-sharing of our global EYLEA™ development expenses with Bayer HealthCare decreased in the first nine months of 2011 compared to the same period in 2010. In the first nine months of 2011, we incurred lower clinical development costs primarily in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 trial in DME, partly offset by higher internal costs in connection with regulatory filings in wet AMD.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreement with Astellas, the $20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In connection with our *VelocImmune*® license agreement with AstraZeneca, which terminated effective as of February 2011, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably through February 2011. In the first nine months of 2011 and 2010, we recognized $18.9 million and $30.0 million, respectively, of technology licensing revenue related to these agreements.

Net Product Sales

For the nine months ended September 30, 2011 and 2010, we recognized as revenue $14.9 million and $20.0 million, respectively, of ARCALYST® net product sales. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the nine months ended September 30, 2010, we recognized as revenue $20.0 million of ARCALYST® net product sales, which included $15.2 million of ARCALYST® net product sales made during the period and $4.8 million of previously deferred net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the first nine months of 2011 and 2010 included $3.2 million and $3.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $482.6 million in the first nine months of 2011 from $410.1 million for the same period of 2010. Our average headcount in the first nine months of 2011 increased to 1,525 from 1,206 in the same period of 2010 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with Sanofi, and 2011 activities in connection with preparing to commercialize EYLEA™ in wet AMD.

Operating expenses in the first nine months of 2011 and 2010 included a total of $40.6 million and $26.3 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the nine months ended September 30, 2011		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 376.9	$ 23.6	$ 400.5
Selling, general, and administrative	63.9	17.0	80.9
Cost of goods sold	1.2		1.2
Total operating expenses	$ 442.0	$ 40.6	$ 482.6

	For the nine months ended September 30, 2010		
Expenses *(In millions)*	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
Research and development	$ 348.7	$ 15.3	$ 364.0
Selling, general, and administrative	33.6	11.0	44.6
Cost of goods sold	1.5		1.5
Total operating expenses	$ 383.8	$ 26.3	$ 410.1

The increase in total Non-cash Compensation Expense in the first nine months of 2011 was primarily attributable to (i) the recognition of higher expense in the first nine months of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to $400.5 million in the first nine months of 2011 from $364.0 million for the same period of 2010. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2011 and 2010:

Research and Development Expenses	**For the nine months ended September 30,**		**Increase**
(In millions)	**2011**	**2010**	**(Decrease)**
Payroll and benefits (1)	$ 126.3	$ 94.3	$ 32.0
Clinical trial expenses	60.5	83.8	(23.3)
Clinical manufacturing costs (2)	80.6	72.6	8.0
Research and other development costs	44.9	40.4	4.5
Occupancy and other operating costs	45.1	38.1	7.0
Cost-sharing of Bayer HealthCare EYLEA™ development expenses (3)	42.9	34.6	8.3
Total research and development expenses	$ 400.5	$ 364.0	$ 36.5

(1) Includes $20.7 million and $13.1 million of Non-cash Compensation Expense for the nine months ended September 30, 2011 and 2010, respectively.

(2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes $2.9 million and $2.2 million of Non-cash Compensation Expense for the nine months ended September 30, 2011 and 2010, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs global EYLEA™ development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's global EYLEA™ development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated global EYLEA™ development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its global EYLEA™ development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, our VIEW 1 trial for EYLEA™ in wet AMD, our Phase 2 trial for EYLEA™ in DME, and our clinical development program for REGN475, which is currently on clinical hold. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing supplies of antibody candidates and EYLEA™, partly offset by lower costs related to manufacturing clinical supplies of ARCALYST®. Research and other development costs increased primarily due to higher costs associated with our antibody programs and filing our BLA for EYLEA™ in wet AMD. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and expanded leased facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's global EYLEA™ development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the second quarter of 2011, and costs associated with ex-U.S. regulatory approval filings for EYLEA™ in wet AMD.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA™ development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**For the nine months ended September 30,**		**Increase**
(In millions)	**2011**	**2010**	**(Decrease)**
ARCALYST®	$ 31.1	$ 48.2	$ (17.1)
EYLEA™	115.4	98.0	17.4
ZALTRAP®	13.6	9.8	3.8
Sarilumab	17.9	20.7	(2.8)
REGN727	24.4	17.1	7.3
Other antibody candidates in clinical development	47.7	51.6	(3.9)
Other research programs & unallocated costs	150.4	118.6	31.8
Total research and development expenses	$ 400.5	$ 364.0	$ 36.5

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2011 and 2010, and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $80.9 million in the first nine months of 2011 from $44.6 million for the same period of 2010 due primarily to increases in compensation expense and recruitment costs principally in connection with higher headcount in the first nine months of 2011, higher commercialization-related costs, primarily in connection with EYLEA™, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons previously described above.

Cost of Goods Sold

Cost of goods sold in the first nine months of 2011 and 2010 was $1.2 million and $1.5 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to $2.8 million in the first nine months of 2011 from $1.5 million in the same period of 2010, due primarily to higher average balances of cash and marketable securities.

Interest expense increased to $11.8 million in the first nine months of 2011 from $6.7 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, private placements of convertible debt, purchases of our equity securities by our collaborators, including Sanofi, revenue earned under our past and present research and development agreements, including our agreements with Sanofi and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Nine months ended September 30, 2011 and 2010

At September 30, 2011, we had $511.7 million in cash, cash equivalents, and marketable securities (including $8.2 million of restricted cash and marketable securities) compared with $626.9 million at December 31, 2010 (including $7.5 million of restricted cash and marketable securities). In addition, as described below, in October 2011, we completed an offering of $400 million aggregate principal amount of convertible senior notes.

Cash (Used in) Provided by Operating Activities

Net cash used in operating activities was $91.4 million in the first nine months of 2011 and net cash provided by operating activities was $140.1 million in the first nine months of 2010. Our net losses of $168.3 million in the first nine months of 2011 and $89.9 million in the first nine months of 2010 included $40.6 million and $26.3 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $23.2 million and $13.6 million in the first nine months of 2011 and 2010, respectively.

At September 30, 2011, accounts receivable decreased by $14.7 million, compared to end-of-year 2010, primarily due to the receipt of the $10.0 million milestone payment in January 2011 from Bayer HealthCare, which was earned in 2010 in connection with the COPERNICUS study of EYLEA™ in CRVO. Prepaid expenses and other assets increased by $6.3 million, compared to end-of-year 2010, primarily due to an increase in capitalized inventories. Our deferred revenue at September 30, 2011 decreased by $32.5 million, compared to end-of-year 2010, primarily due to the amortization of previously received and deferred $20.0 million payments under our license agreements with AstraZeneca and Astellas, as well as amortization of previously received deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $35.3 million at September 30, 2011, compared to end-of-year 2010, due primarily to higher payroll-related liabilities.

At September 30, 2010, accounts receivable increased by $16.7 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with Sanofi. Also, our deferred revenue balances at September 30, 2010 increased by $172.7 million, compared to end-of-year 2009, primarily due to (i) the receipt of the $165.0 million up-front payment from Astellas, as described above, which was deferred and will be recognized ratably over the seven-year period that commenced in mid-2011, (ii) the receipt of the $20.0 million annual payments from AstraZeneca and Astellas in the first half of 2010, which were deferred and recognized ratably over the ensuing year, and (iii) Sanofi's funding of $21.1 million of agreed-upon costs incurred by us during the first nine months of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original $85.0 million up-front payment received from Sanofi. These increases were partially offset by amortization of previously received deferred payments under our Sanofi and Bayer HealthCare collaborations. At September 30, 2010, accounts payable, accrued expenses, and other liabilities increased by $28.0 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $162.4 million in the first nine months of 2011, compared with net cash used in investing activities of $82.4 million in the first nine months of 2010. In the first nine months of 2011, sales or maturities of marketable securities exceeded purchases by $209.0 million, whereas in the first nine months of 2010, purchases of marketable securities exceeded sales or maturities by $13.2 million. Capital expenditures in the first nine months of 2011 and 2010 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased facilities in Tarrytown, New York.

Cash Provided by Financing Activities

Net cash provided by financing activities was $22.8 million in the first nine months of 2011 and $60.5 million in the first nine months of 2010. In the first nine months of 2010, we received $47.5 million from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with Financial Accounting Standards Board (FASB) authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $24.0 million in the first nine months of 2011 and $13.8 million in the first nine months of 2010.

Fair Value of Marketable Securities

At September 30, 2011 and December 31, 2010, we held marketable securities whose aggregate fair value totaled $304.4 million and $513.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	September 30, 2011		December 31, 2010	
Investment type	**Fair Value**	**Percent**	**Fair Value**	**Percent**
Unrestricted				
U.S. government obligations	$ 241.5	79%	$ 434.4	85%
U.S. government guaranteed corporate bonds	36.8	12%	64.0	13%
Municipal bonds	14.7	5%	1.6	
Equity securities	3.1	1%	3.6	1%
U.S. government guaranteed collateralized mortgage obligations	1.0	1%	2.1	
Mortgage-backed securities	0.1		1.1	
Total unrestricted marketable securities	297.2	98%	506.8	99%
Restricted				
U.S. government obligations	7.2	2%	7.1	1%
Total marketable securities	$ 304.4	100%	$ 513.9	100%

In addition, at September 30, 2011 and December 31, 2010, we had $207.3 million and $113.0 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $45.9 million and $67.4 million for the first nine months of 2011 and 2010, respectively. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, Sanofi has funded $3.0 million and $21.1 million, respectively, of agreed-upon capital expenditures incurred by us during the first nine months of 2011 and 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at September 30, 2011 and 2010.

We expect to incur capital expenditures of approximately $10 to $20 million during the remainder of 2011 primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by Sanofi, with the remaining amount to be funded by our existing capital resources.

Offering of Convertible Senior Notes

On October 17, 2011, we announced an offering of $400 million aggregate principal amount of 1.875% convertible senior notes due October 1, 2016. The offering closed on October 21, 2011. The initial purchaser of the notes has a 13-day option to purchase up to an additional $60 million aggregate principal amount of notes on the same terms and conditions. The notes were offered by the initial purchaser only to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933.

The notes will pay interest semi-annually on April 1 and October 1 at an annual rate of 1.875%, and will mature on October 1, 2016, unless earlier converted or repurchased. The notes will be convertible, subject to certain conditions, into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our option. The initial conversion rate for the notes will be 11.9021 shares of Common Stock (subject to adjustment in certain circumstances) per $1,000 principal amount of the notes, which is equal to an initial conversion price of approximately $84.02 per share.

In connection with the offering of the notes, we entered into convertible note hedge and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of our Common Stock that initially underlie the notes, and are intended to reduce the dilutive impact of the conversion feature of the notes. The warrant transactions will have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of our Common Stock, at our option.

The net proceeds from the notes offering were approximately $391.3 million after deducting the initial purchaser's discount and estimated offering expenses (and will be approximately $450.1 million if the initial purchaser exercises in full its option to purchase additional notes). In addition, the cost of the initial convertible note hedge, after taking into account the proceeds received by us from the warrant transactions, was $23.7 million. If the initial purchaser exercises its option to purchase additional notes, we may use net proceeds from the sale of the additional notes to enter into additional convertible note hedge and warrant transactions. We intend to use the remaining net proceeds for general corporate purposes.

Funding Requirements

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our ZALTRAP® and antibodies collaborations are, generally, fully funded by Sanofi. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our EYLEA™ collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 40-50% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and EYLEA™). For 2011, we also currently estimate that approximately 10-15% of our funding requirements will be directed toward the planned commercialization of our late-stage product candidates; approximately 20-25% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with Sanofi and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, whether or not our late-stage product candidates receive regulatory approval, the market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, together with the net proceeds of our offering of convertible senior notes, as described above, and funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs for at least the next several years. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credit totaling $4.2 million, including a $3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of September 30, 2011, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2011, we announced our offering of convertible senior notes, as described above. In addition, in October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately, and our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement. There is no assurance, however, that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure additional funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In December 2010, the FASB provided authoritative guidance on how pharmaceutical manufacturers should recognize and classify in their income statement annual fees mandated by the Patient Protection and Affordable Care Act (PPACA) as amended by the Health Care and Education Reconciliation Act. This guidance became effective for calendar years beginning after December 31, 2010. The adoption of this guidance did not have an impact on our financial statements as the fee does not currently apply to us. Our one marketed product, ARCALYST® for the treatment of CAPS, has been approved as an orphan drug and orphan drugs are not subject to this annual fee.

In June 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, an entity will have the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This amendment, therefore, eliminates the currently available option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendment does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. We will adopt this amended guidance for the fiscal year beginning January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance will not have any other effect on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $1.7 million and $0.4 million decrease in the fair value of our unrestricted investment portfolio at September 30, 2011 and 2010, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at September 30, 2011 compared to the same period of 2010.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We recognized an other-than-temporary impairment charge related to a marketable security of $0.1 million in the first nine months of 2010. During the first nine months of 2011, we did not recognize any other-than-temporary impairment charges.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current ordinary course legal proceedings to have a material adverse effect on our business or financial condition.

As previously reported, on November 19, 2010, we filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to our VEGF Trap (aflibercept) infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon our submission to the FDA of a BLA for EYLEA™ (aflibercept injection) for the treatment of wet AMD, we filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, we and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, we voluntarily dismissed our original complaint in favor of proceeding with our second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, we replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of our prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. We believe Genentech's counterclaims are without merit and intend to continue to defend against them vigorously.

We have initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy, and may initiate other actions in other countries outside the U.S.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2011, we had a cumulative loss of $1.2 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our substantial losses will continue as we conduct our research and development activities and prepare for possible commercialization of our product candidates.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of those product(s). We believe our existing capital resources, together with the net proceeds of our October 2011 offering of convertible senior notes and funding we are entitled to receive under our collaboration agreements, will enable us to meet anticipated operating needs for at least the next several years; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease or be delayed, or our expenses may increase, which could result in our capital being consumed significantly before that time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our late-stage product candidates, manufacturing scale-up, expenses related to clinical trials testing ARCALYST®, EYLEA™, or REGN846, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being developed in collaboration with Sanofi.

We may require additional financing in the future and we may not be able to raise additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements, if even available given the current uncertainties in the global credit and financial markets, may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs. Even if we obtain regulatory approval for our product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of September 30, 2011, our cash, cash equivalents, and marketable securities totaled $511.7 million (including $8.2 million of restricted cash and marketable securities). We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Unrestricted and restricted marketable securities totaled $304.4 million at September 30, 2011, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. The current economic environment and the volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to the Development and Approval of Our Product Candidates

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of EYLEA™ for the treatment of wet AMD and other ophthalmologic diseases, which has not yet been approved by the FDA or by regulatory authorities in countries outside the U.S. The FDA recently extended its target action date for the EYLEA™ BLA by three months to November 18, 2011. If there are additional material delays in obtaining marketing approval for EYLEA™, or such approval is not obtained in the U.S. or in countries outside the U.S., our business, results of operations, and financial condition will be materially harmed.

The FDA has substantial discretion in deciding whether or not EYLEA™ should be granted approval in the U.S. based on the benefits and risks of EYLEA™ in treating the particular ophthalmologic diseases in which it is being studied in clinical trials. In February 2011, we submitted a BLA for EYLEA™ for the treatment of wet AMD to the FDA. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the BLA was August 20, 2011. On August 16, 2011, FDA notified us that it had extended its target date to complete the priority review of the EYLEA™ BLA for the treatment of wet AMD to November 18, 2011, which is a three month extension from the original action date. The extension is a result of the agency classifying responses to questions regarding the CMC section of the BLA as a major amendment to the BLA. The new action date gives the agency additional time to review the additional information. However, the FDA is not under any legal obligation to complete its review of the BLA or to render a decision within this extended timeframe. It is not unusual for the FDA's review of and/or rendering a decision with respect to a BLA that has been granted Priority Review to extend the action date. For instance, the FDA may request additional clinical or other data or information, including by issuing a complete response letter which may require that we submit additional clinical or other data or impose other conditions that must be met in order to secure final approval of our BLA. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The granting of Priority Review designation for our BLA does not change the standards for approval and does not ensure that EYLEA™ for the treatment of wet AMD will be approved by November 18, 2011 or ever. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA voted unanimously to recommend that the FDA approve EYLEA™ for the treatment of wet AMD at a dose of 2 mg every eight weeks following three initial doses given every four weeks. The FDA will consider the committee's recommendation in its review of our BLA, but it is not bound by the committee's recommendation and the FDA may not follow the committee's recommendation.

Whether EYLEA™ is approved by the FDA for the treatment of wet AMD, and the timing thereof, will depend on many factors, including the following:

- whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of EYLEA™ demonstrates that it is safe and effective as a treatment for wet AMD;
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for EYLEA™ are adequate, that the labeling is satisfactory, and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient;
- whether or not FDA is satisfied with our responses to its inquiries in connection with the three month extension of the action date on the EYLEA™ BLA for the treatment of wet AMD, the timing and nature of additional or follow-up comments and questions, or those of any advisers to the FDA if the FDA seeks external advice, regarding our BLA and the FDA's satisfaction with our responses to its inquiries, the time required to respond to any such additional or follow-up comments and questions, and to obtain final labeling, and any other or additional delays that may be associated with the BLA review process in addition to the three month delay already incurred.

In June 2011, Bayer HealthCare submitted regulatory applications for marketing approval of ELYEA™ in wet AMD in the European Union and Japan. Analogous regulatory authorities in these and other countries outside the U.S. have similar discretion to the FDA as to approval of EYLEA™ in those countries.

If we experience material delays in obtaining marketing approval for EYLEA™ for wet AMD, we will not receive product revenues during the delay, which would negatively affect our business, results of operations, financial condition, and cash flow. Such delays may also increase the challenge of competitive products as doctors and patients continue to use existing therapies. If we do not obtain approval to market EYLEA™ for wet AMD in the United States, our business, results of operations, financial condition, and cash flows will be materially harmed. Similarly, but independently, if Bayer HealthCare does not obtain approval to market EYLEA™ in the European Union or Japan, or if there are material delays in obtaining such approvals, our business, results of operations, financial condition, and cash flow will be harmed.

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them, which would materially and negatively impact our business, results of operations, and prospects.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, EYLEA™ for the treatment of ophthalmologic diseases, and/or ZALTRAP® for one or more oncology indications, the value of our company, our results of operations and our prospects will be materially harmed. As with our BLA for EYLEA™ for the treatment of wet AMD, our other product candidates, including ZALTRAP® for previously treated mCRC, EYLEA™ for CRVO and DME, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, may not receive regulatory approval. If we are unable to obtain such approval(s), or if we are materially delayed in doing so, our business, results of operations, and prospects will be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the U.S., we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for FDA approval of ARCALYST®, and the EMA approval of rilonacept, for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the U.S. or any other country. We may never receive regulatory approval for any of our current or future product candidates.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs and could substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the shipment and storage of the product. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, and following approval in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the U.S., we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process and requirements include all of the risks associated with FDA approval as well as country specific regulations, and actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Whether or not we obtain FDA approval for a product in the U.S., we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, regulatory approval for our product candidates may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon that drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, financial condition, results of operations, and prospects may be materially harmed.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are testing ZALTRAP® and EYLEA™ in a number of late-stage clinical trials in various indications and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials.

In April 2011 we announced that our Phase 3 VELOUR trial of ZALTRAP® met its primary endpoint of improving overall survival in the treatment of previously treated mCRC, and that based upon these positive results, we and Sanofi plan to submit regulatory applications for marketing approval to the FDA and EMA by the end of 2011. However, the expected timing for this submission may not be met and even if submitted such applications may not be accepted for filing or ultimately approved. ZALTRAP® is also in a Phase 3 clinical trial in combination with a standard chemotherapy regimen for the treatment of first-line androgen independent prostate cancer. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that ZALTRAP® will be safe or effective in this cancer setting. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (Bevacizumab Injection), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of ZALTRAP® in prostate cancer.

We are testing EYLEA™ in Phase 3 trials for the treatment of wet AMD, the treatment of CRVO, and the treatment of DME. As described above, in February 2011, we submitted a BLA to the FDA for marketing approval of EYLEA™ in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. On August 16, 2011, FDA notified us that it had extended its target date to complete the priority review of the EYLEA™ BLA for the treatment of wet AMD to November 18, 2011, which is a three month extension from the original action date. Although we reported positive Phase 3 trial results with EYLEA™ in wet AMD after one year of treatment, the Phase 3 trials will continue for an additional year and there is a risk that the results from the second year of the studies could differ from the previously reported results; such difference could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval.

We also reported positive Phase 3 trial results with EYLEA™ in CRVO after six months of treatment and, based on these results, intend to submit a regulatory application to the FDA for marketing approval in the U.S. of EYLEA™ in CRVO by the end of 2011. However, these trials are not all completed, and there is a risk that one-year results could differ from six-month results, and such final results could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval. There can be no assurance that we will meet our expected timing for this submission, the submission will be accepted for filing, or if or when we will receive regulatory approval for EYLEA™ in CRVO.

We also reported positive results of a Phase 2 trial of EYLEA™ for the treatment of DME and that we have initiated a Phase 3 program in that indication. A number of other potential new drugs and biologics which showed promising results in Phase 1 and 2 clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals, and this could occur with respect to subsequent clinical trials of EYLEA™ for the treatment of DME.

Based on the results of three Phase 3 studies, we have submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. However, the expected timing may not be met, the application may not be accepted for filing, and the FDA may not grant such approval or such approval may be substantially delayed. The FDA could also require us to provide additional clinical data in connection with this application. For example, in June 2011, following two positive Phase 3 trials, the Arthritis Advisory Committee of the FDA, voted to recommend against approval in a gout indication for Ilaris® (canikinumab), Novartis' IL-1 inhibitor which works through a similar mechanism as ARCALYST® and, in August 2011, Novartis received a Complete Response letter from the FDA requesting additional information, including clinical data to evaluate the benefit-risk profile of Ilaris® in refractory patients.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP® as a first-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of ARCALYST® for the treatment of CAPS and in clinical trials of some of our product candidates, and may also occur with the more widespread use of ZALTRAP®, EYLEA™, and/or ARCALYST® for the prevention of gout flares if they receive regulatory approval, which could cause our regulatory approval(s) to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or if the product candidate has received regulatory approval such approval may be revoked, which would severely harm our business.

ZALTRAP® is being studied for the potential treatment of certain types of cancer and our EYLEA™ candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAP® and EYLEA™ in each of the indications for which we are studying these product candidates. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including ZALTRAP® delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like EYLEA™, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development and/or commercialization of ZALTRAP® for the treatment of cancer or EYLEA™ for the treatment of diseases of the eye.

As more patients begin to use ARCALYST® if it receives regulatory approval for the prevention of gout flares in patients initiating uric acid-lowering therapy, and to the extent it is tested in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Ilaris® (canakinumab), a registered trademark of Novartis, Kineret® (anakinra) and Enbrel® (etanercept), registered trademarks of Amgen, and Remicade® (infliximab) a registered trademark of Centocor Ortho Biotech, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. As noted above, in June 2011, following two positive Phase 3 trials, the Arthritis Advisory Committee of the FDA voted to recommend against approval in a gout indication for Ilaris®, Novartis' IL-1 inhibitor which works through a similar mechanism as ARCALYST® and, in August 2011, Novartis received a Complete Response letter from the FDA requesting additional information, including clinical data to evaluate the benefit-risk profile of Ilaris® in refractory patients.

Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in the current or future approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. The FDA Arthritis Advisory Committee scheduled for September 13, 2011 to discuss possible safety issues related to anti-NGF compounds has been postponed. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so neutralizing antibodies may be detected at a later date, in some cases even after pivotal clinical trials have been completed.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our own employees, our collaborators or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the U.S. may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Patent applications filed in the U.S. may also be challenged by third parties who file a request for post-grant review under the America Invents Act of 2011, beginning on September 16, 2012. We expect that post-grant review proceedings will become common in the U.S. and will be costly to defend. We have pending patent applications in the U.S. Patent and Trademark Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third-party patents or other proprietary rights, and the costs and expenses of ongoing patent litigation have been and will likely continue to be significant.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune®* technology, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We are aware of issued patents and pending patent applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAP® or EYLEA™ infringe any valid claim in these patents or patent applications. As described above under Part II, Item 1 ("Legal Proceedings"), in November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York, seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. In April 2011, we and Genentech entered into a Joint Stipulation whereby Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the case for lack of subject matter jurisdiction. On April 25, 2011, Genentech filed an answer to our complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 11, 2011, Genentech filed an amended answer and counterclaim, again denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to our VEGF Trap have infringed or will infringe claims of four of the five Davis-Smyth patents. In its amended answer and counterclaim, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. On May 25, 2011, we replied to Genentech's amended answer and counterclaim, denying Genentech's counterclaims, and denying that any of our prior or planned activities relating to VEGF Trap infringe any valid claim of the Davis-Smyth patents. We believe Genentech's counterclaims are without merit and intend to continue to defend against them vigorously. However, it is possible that there could be an adverse determination or judgment in this litigation that would materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of ZALTRAP® or EYLEA™, or resulting in a damage award. In addition, irrespective of the outcome of this litigation, we have incurred and will likely continue to incur significant costs and expenses associated with this matter, which has negatively affected, and will likely continue to negatively affect, our results of operations. We have initiated patent-related actions against Genentech in Germany, the United Kingdom, and Italy, and may initiate other actions in other countries outside the U.S., which could have similar or other adverse outcomes that would materially harm our business and which, irrespective of the outcomes, may also entail significant costs and expenses.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that sarilumab infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover sarilumab.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, ZALTRAP®, nor EYLEA™ are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the U.S.

Further, we are aware of a number of other third-party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

Patent holders in addition to Genentech could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our drug candidates, including EYLEA™ or our other late-stage product candidates, infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the U.S or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "*If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed*", the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could be material to us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the U.S. and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the PPACA, enacted in 2010, there is now a new, abbreviated path in the U.S. for regulatory approval of biosimilar versions of biological products. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this new regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the U.S. and could be shortened.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in U.S. regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

We have and rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to successfully commercialize our product candidates if they receive regulatory approval and also to continue to develop our clinical candidates.

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA™, ZALTRAP®, and ARCALYST® for the treatment of gout flares in sufficient commercial quantities if these late-stage product candidates were all to receive regulatory approval, and (b) our earlier stage product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. We rely entirely on third-parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through such third parties manufacture and supply sufficient commercial quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, third-party manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products, our business, financial condition, results of operations, and prospects may be materially harmed.

Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our late-stage product candidates if they are approved for marketing and could jeopardize our current and future clinical development programs.

Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our manufacturing and supply chain operations. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize EYLEA™, ZALTRAP®, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment if they receive regulatory approval, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, financial condition, and results of operations could be materially harmed.

Our ability to manufacture our products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe third-party patents.

Our ability to continue to manufacture ARCALYST®, EYLEA™, and ZALTRAP® in our Rensselaer, New York facilities, or to utilize third parties to produce our products or perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products where those intellectual property rights apply which could materially harm our business, results of operations, and prospects.

If the launch of our late-stage product candidates, or any of our clinical programs, are delayed or discontinued, we may face costs related to unused capacity at our manufacturing facilities and at the facilities of third parties performing fill/finish services or other steps in our manufacture and supply chain.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product of ARCALYST® for the treatment of CAPS and of clinical and preclinical candidates for ourselves and our collaborations, and plan to use such facilities to produce bulk product for commercial supply of our late-stage product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of any of our late-stage product candidates is delayed or does not occur, or if such products are launched and subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing fill/finish services for us.

Third-party service or supply failures, or other failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Also, certain raw materials necessary for the manufacture and formulation of ARCALYST® and of our product candidates, including EYLEA™ and ZALTRAP®, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of ARCALYST® and our product candidates. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® for the treatment of CAPS and to manufacture and supply commercial quantities of EYLEA™, ZALTRAP®, and ARCALYST® for the prevention of gout flares if they receive regulatory approval, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third-party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple product candidates at our facility in Rensselaer, New York, including ARCALYST®, EYLEA™, and ZALTRAP®, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business and prospects. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, financial condition, and prospects.

Risks Related to Commercialization of Products

Even if we receive regulatory approval to market EYLEA™ or our other late-stage product candidates, we may be unsuccessful in commercializing them, which would materially delay or prevent our achieving profitability.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture and commercialize those products. Even if we obtain regulatory approval for our product candidates, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, results of operations, and financial condition would be severely harmed.

In particular, we cannot be sure that EYLEA™ for the treatment of wet AMD will be commercially successful in the pharmaceutical market even if we obtain marketing approval for EYLEA™ for such indication in a timely manner. In addition to the challenges we face related to a company launching its first major commercial drug, as described in detail in the risk factor immediately below, we and Bayer HealthCare will face intense competition from Lucentis® and from off-label use of Avastin®, both of which have been on the market for a number of years. We expect that the initial commercial success of EYLEA™ for the treatment of wet AMD if it is approved for marketing will depend on many factors, including the following:

- the effectiveness of our and Bayer HealthCare's commercial strategies for the launch and marketing of EYLEA™ in and outside the U.S., respectively, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA™ with third parties who perform fill/finish or other steps in the manufacture of EYLEA™ to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA™;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA™ of every 2 months as compared to the monthly dosing regimen of Lucentis®, and the willingness of retinal specialists and patients to switch from Lucentis® or off-label use of Avastin® to EYLEATM for the treatment of wet AMD;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payors, including Medicare and Medicaid in the U.S. and other government and private payors in the U.S. and foreign jurisdictions; and
- the effect of new health care legislation currently being implemented in the United States.

While we believe that EYLEA™ for the treatment of wet AMD will have a commercially competitive profile if it is approved for marketing in the U.S. or elsewhere, we cannot predict whether ophthalmologists, particularly retinal specialists, and patients, will accept or utilize EYLEA™. Our and Bayer HealthCare's efforts to educate the relevant medical community and third-party payors regarding the benefits of EYLEA™ for the treatment of wet AMD will require significant resources and may not be successful in achieving our objectives. If EYLEA™ is approved for marketing but does not achieve significant market acceptance for the treatment of wet AMD, our ability to achieve profitability would be materially impaired or delayed.

If we are unable to establish and effectively deploy and manage sales, marketing, and distribution capabilities in the applicable markets or to enter into agreements with third parties to do so, even if our late-stage product candidates receive regulatory approval we will be unable to successfully launch and commercialize those products in those markets, which would materially harm our business, operating results, and financial condition.

We are selling ARCALYST® ourselves in the U.S. for the treatment of CAPS, primarily through third-party service providers. We are establishing our own sales, marketing, and distribution organization in anticipation of receiving regulatory approval to market and sell EYLEA™ in the U.S. for the treatment of wet AMD, and in anticipation of filing for and receiving regulatory approval to market and sell EYLEA™ in the U.S. for the treatment of CRVO. However, even if we can fully establish this organization in a timely fashion, we may be unsuccessful in achieving a successful launch and commercialization of EYLEA™ in the U.S., which would materially harm our business, operating results, financial condition, and prospects.

We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if it receives regulatory approval. If we are unable to obtain these capabilities, either by developing our own organizations or entering into agreements with others to provide these functions, even if ARCALYST® for the prevention of gout flares receives marketing approval, we will not be able to successfully launch and commercialize this product, which would also materially harm our business, operating results, financial condition, and prospects.

We have no experience in sales, marketing, or distribution of products in substantial commercial quantities or in establishing and managing the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network, and we may be unable to establish such infrastructure on a timely basis. In building a field force in anticipation of the possible approval and launch in the U.S. of EYLEA™ in wet AMD and other ophthalmologic indications for which it is currently in Phase 3 clinical trials, we may be unable to successfully recruit and retain within the required time frame an adequate number of qualified sales representatives. To the extent we determine to utilize third parties to provide sales, marketing, or distribution capabilities for ARCALYST® for the prevention of gout flares or any of our other products if they receive regulatory approval, we may encounter difficulties in retaining such parties on acceptable terms. Even if we hire qualified sales and marketing personnel, and establish the required infrastructure we need to support our objectives, or enter into marketing and distribution agreements with third parties on acceptable terms, we may not do so in an efficient manner or on a timely basis. We may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution capabilities necessary to successfully market and sell in the U.S. EYLEA™, ARCALYST® for the prevention of gout flares, or any of our other product candidates if they receive regulatory approval in the U.S. and as to which we retain sales and marketing responsibility in that market. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Our expenses associated with building up and maintaining a sales force and distribution capabilities may be disproportional, particularly in the near term, compared to the revenues we may be able to generate on sales in the U.S. of EYLEA™ or ARCALYST® for the prevention of gout flares. Ultimately neither we nor our collaborators may be successful in commercializing EYLEA™, ZALTRAP®, ARCALYST® for the prevention of gout flares, or any of our other product candidates.

Under the terms of our collaboration agreement, Sanofi has primary responsibility for sales, marketing, and distribution of ZALTRAP® in cancer indications, should it be approved in the future by regulatory authorities for marketing.

We currently have no sales, marketing, commercial, or distribution capabilities outside the U.S. Under the terms of our license and collaboration agreement with Bayer HealthCare, we will rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA™ in countries outside the U.S. should it be approved for marketing in such countries.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain given their method of administration, and because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

As previously noted, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Some of these molecules are further along in development than ZALTRAP® and may offer competitive advantages over our molecule. Each of Pfizer, Onyx Pharmaceuticals, Inc. (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin®, and their extensive, ongoing clinical development plan for Avastin® in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support ZALTRAP® for those indications and to obtain regulatory approval of ZALTRAP® in those indications. This may delay or impair our ability to successfully develop and commercialize ZALTRAP® for various cancer indications. In addition, even if ZALTRAP® is approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® for the treatment of wet AMD, CRVO, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following retinal vein occlusion (RVO), CRVO, and branch retinal vein occlusion (BRVO). Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, third-party repackaged versions of Genentech's approved VEGF antagonist, Avastin®.

The National Eye Institute (NEI) and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT) were reported in April 2011 and indicated that Avastin® dosed monthly was non-inferior to Lucentis® dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Even if our BLA for EYLEA™ for the treatment of wet AMD is approved, it may be difficult for EYLEA™ in this or other eye indications for which it may be approved to compete against Lucentis® and off-label use of Avastin® because doctors and patients have had significant experience using these medicines. Moreover, the recently reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA™ will face in this or other eye indications for which it may be approved. In addition, while we believe that ZALTRAP® would not be well tolerated if administered directly to the eye, if ZALTRAP® is approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage ZALTRAP® for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA™ if it is approved for wet AMD or other eye indications.

The availability of highly effective FDA approved Tumor Necrosis Factors-antagonists (TNF-antagonists) such as Enbrel®, Remicade®, Humira® (adalimumab), a registered trademark of Abbott Laboratories, Simponi® (golimumab), a registered trademark of Johnson & Johnson, the IL-1 receptor antagonist Kineret®, Ilaris® (canakinumab), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in indications other than CAPS, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients have had significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma Ltd. (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the U.S. and Europe for Ilaris®, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. Ilaris® is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, Ilaris® is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for the treatment of CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and have submitted a supplemental BLA filing for U.S. regulatory approval in this indication. In January 2011, Novartis announced that the results of two Phase 3 studies with Ilaris® focused on reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout were positive. Novartis has also reported that regulatory filings for the use of Ilaris® in gouty arthritis have been completed in the European Union in 2010 and in the U.S. in the first quarter of 2011, based on the results of these two Phase 3 studies. Ilaris® is dosed less frequently for the treatment of CAPS, and if it is approved for the treatment of gout, it may be perceived by some physicians as offering competitive advantages over ARCALYST®, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other NSAIDS, are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST® in these diseases.

Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune®* technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor/Johnson & Johnson, and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects.

The successful commercialization of our late-stage product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the U.S., and these payers may not agree to cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, operating results, and financial condition.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDS. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected in a material manner if U.S. and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services (CMS) and other federal and state agencies. Further, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-label Avastin® rather than Lucentis® for the treatment of wet AMD. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since EYLEA™ for the treatment of wet AMD and other eye diseases, ZALTRAP® for oncology indications, and ARCALYST® for the prevention of gout flares will likely be too expensive for most patients to afford without health insurance coverage, if these products are approved for marketing but are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the U.S., our ability to successfully commercialize these products would be materially adversely impacted. Third-party payers, including Medicare and Medicaid in the U.S., may not cover and/or reimburse for these products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Regulatory and Litigation Risks

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved product, ARCALYST® for the treatment of CAPS, or EYLEA™, ZALTRAP®, or ARCALYST® for the prevention of gout flares if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of our third-party fill/finish or other providers. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell approved products, in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the PPACA pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the Public Company Accounting Oversight Board (PCAOB), the Securities and Exchange Commission (SEC) and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation (so-called "say on pay") and proxy access. On January 25, 2011, the SEC adopted final rules concerning "say on pay". Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2010, which report is included in our Annual Report on Form 10-K for the fiscal year ended on that date. However, management or our independent registered public accounting firm may not be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with Sanofi is terminated, our business operations and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from Sanofi to support our target discovery and antibody research and development programs. Sanofi has committed to pay up to $160 million per year, or a total of $1.28 billion, between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. Sanofi has a one-time option to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. If this downward adjustment occurs, it will reduce our resources available for antibody discovery activities and negatively affect our clinical pipeline. Sanofi also initially funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that Sanofi elects to co-develop with us. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us, such as REGN727, sarilumab, REGN668, REGN421, REGN910, REGN475, and REGN728, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the U.S. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. If Sanofi terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, results of operations and prospects would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. Even though none of the antibodies from this collaboration may ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with Sanofi for ZALTRAP® is terminated, or Sanofi materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize ZALTRAP® in the time expected, or at all, would be materially harmed.

We rely heavily on Sanofi to lead much of the development of ZALTRAP®. Sanofi initially funds all of the development expenses incurred by both companies in connection with the ZALTRAP® program. If the ZALTRAP® program continues, we will rely on Sanofi to assist with funding the ZALTRAP® program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the U.S., and lead the commercialization of ZALTRAP®. While ZALTRAP® may not ever be successfully developed and commercialized, if Sanofi fails to perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize ZALTRAP® in cancer indications will be significantly adversely affected. Sanofi has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If Sanofi were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of ZALTRAP® and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the Sanofi collaboration agreement for ZALTRAP® would create substantial new and additional risks to the successful development and commercialization of ZALTRAP®.

If our collaboration with Bayer HealthCare for EYLEA™ is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to continue to develop EYLEA™ and commercialize EYLEA™ outside the U.S. in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development, and the commercialization outside the U.S., of EYLEA™. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global EYLEA™ development program. As the EYLEA™ program continues, we will continue to rely on Bayer HealthCare to assist with funding the EYLEA™ development program, continue to lead the development of EYLEA™ outside the U.S., obtain regulatory approval outside the U.S., and provide all sales, marketing, and commercial support for the product outside the U.S. In particular, Bayer HealthCare has responsibility for selling EYLEA™ outside the U.S. using its sales force. While we cannot assure you that EYLEA™ will receive regulatory approval in or outside the U.S. or be successfully commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA™ outside the U.S. will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA™ outside the U.S. and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the U.S. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA™, particularly outside the U.S.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers, fill/finish, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates, and will also depend on some of these third parties in connection with the commercialization of our late-stage product candidates if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, Good Laboratory Practices (GLPs), or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for and successfully commercializing, our product candidates.

We rely on third-party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. Despite our arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, our sales of ARCALYST® for the treatment of CAPS will suffer.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we prepare for commercialization in the U.S. of our late-stage product candidates should they receive regulatory approval, we will also be highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion, and computer viruses which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others.

Such disruptions and breaches of security could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our currently pending or future application(s) for regulatory approval of our late-stage product candidate(s);
- announcement of submission of an application for regulatory approval of one or more of our late-stage product candidates;
- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results; in particular, if EYLEA™ or any of our other late-stage product candidates is approved for marketing, and our revenues, market share, and/or market acceptance of EYLEA™ or such other products do not meet the expectations of investors or analysts;
- third-party claims that our products or technologies infringe their patents;
- third-party challenges to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our product candidates, including EYLEA™, ZALTRAP®, or ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy;
- pricing or reimbursement actions or decisions by government authorities or insurers affecting the coverage or reimbursement of any of our product candidates or competitive products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2011, our six largest shareholders plus Leonard S. Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 62.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2011. In September 2003, Sanofi (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 Sanofi purchased an additional 12,000,000 newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with Sanofi, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, Sanofi purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of September 30, 2011, Sanofi beneficially owned 15,816,953 shares of our Common Stock, representing approximately 17.5% of the shares of Common Stock then outstanding. If Sanofi, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2011, holders of Class A Stock held 18.9% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2011:

- our current executive officers and directors beneficially owned 11.0% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2011, and 24.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2011; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 62.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2011. In addition, these seven shareholders held 65.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2011.

Pursuant to an investor agreement, as amended, Sanofi has agreed to vote its shares, at Sanofi's election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with Sanofi, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder", a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."*

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with Sanofi or our ZALTRAP® collaboration with Sanofi, Sanofi will be bound by certain "standstill" provisions, as amended, which contractually prohibit Sanofi from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of our company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of our company. Many of our stock options issued under our 2000 Long-Term Incentive Plan, as amended and restated, may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

Risks Relating to Our Convertible Senior Notes and Related Hedge Transactions

The convertible note hedges and warrant transactions may affect the trading price of our Common Stock.

In connection with our offering of our 1.875% Convertible Senior Notes due October 1, 2016, we entered into convertible note hedge transactions with four financial institutions (the "hedge counterparties"). The convertible note hedge transactions are expected to reduce the potential dilution to our Common Stock and/or offset potential cash payments in excess of the principal amount of the notes, as the case may be upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments as the case may be as required under the convertible note hedge documents, we would not receive the benefit of such transaction. Separately, we also entered into warrant transactions with the hedge counterparties. The warrant transactions could separately have a dilutive effect from the issuance of Common Stock pursuant to the warrants.

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may enter into various derivative transactions with respect to our Common Stock, and may enter into, or may unwind, various derivative transactions and/or purchase or sell our Common Stock or other securities of ours in secondary market transactions prior to maturity of the notes (and are likely to do so during any conversion period related to any conversion of the notes). These activities could have the effect of increasing or preventing a decline in, or could have a negative effect on, the value of our Common Stock and could have the effect of increasing or preventing a decline in the value of our common stock during any cash settlement averaging period related to a conversion of the notes.

In addition, we intend to exercise options under the convertible note hedge transactions whenever notes are converted. In order to unwind its hedge position with respect to the options we exercise, the hedge counterparties and/or their affiliates may sell shares of our Common Stock or other securities in secondary market transactions or unwind various derivative transactions with respect to our Common Stock during the cash settlement averaging period for the converted notes. The effect, if any, of any of these transactions and activities on the trading price of our Common Stock or the notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our Common Stock and the value of the notes. The derivative transactions that the hedge counterparties and/or their affiliates expect to enter into to hedge these transactions may include cash-settled equity swaps referenced to our Common Stock. In certain circumstances, the hedge counterparties and/or their affiliates may have derivative positions that, when combined with the hedge counterparties' and their affiliates' ownership of our Common Stock, if any, would give them economic exposure to the return on a significant number of shares of our Common Stock.

The fundamental change provisions of our convertible notes and certain of the terms of the convertible note hedge and warrant transactions may delay or prevent an otherwise beneficial takeover attempt of us.

The fundamental change purchase rights, which will allow noteholders to require us to purchase all or a portion of their notes upon the occurrence of a fundamental change, as defined in the indenture governing the notes, and the provisions requiring an increase to the conversion rate for conversions in connection with make-whole fundamental changes, as set forth in the indenture, may in certain circumstances delay or prevent a takeover of us and the removal of incumbent management that might otherwise be beneficial to investors. In addition, upon the occurrence of certain extraordinary events, the convertible note hedge transactions would be exercised upon the conversion of notes, and the warrant transactions may be terminated. It is possible that the proceeds we receive upon the exercise of the convertible note hedge transactions would be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. Such differences may result in the acquisition of us being on terms less favorable to our shareholders than it would otherwise be.

We are subject to counterparty risk with respect to the convertible note hedge transactions.

The hedge counterparties for the convertible note hedge transactions are financial institutions, and we will be subject to the risk that any or all of them might default under the convertible note hedge transactions. Our exposure to the credit risk of the hedge counterparties will not be secured by any collateral. Recent global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions, including the bankruptcy filing by Lehman Brothers Holdings Inc. and its various affiliates. If a hedge counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under our transactions with that hedge counterparty. Furthermore, if a hedge counterparty defaults, we will not be able to set off our obligations to the hedge counterparty under the warrant transactions against the obligations of such hedge counterparty to us under the convertible note hedge transactions, which may result in significant losses to us. Our exposure will depend on many factors but, generally, the increase in our exposure will be correlated to the increase in the market price and in the volatility of our Common Stock. In addition, upon a default by a hedge counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our Common Stock. We can provide no assurances as to the financial stability or viability of the hedge counterparties.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On October 21, 2011, we issued and sold $400 million aggregate principal amount of 1.875% Convertible Senior Notes due October 1, 2016 to the initial purchaser in a private placement pursuant to exemptions from the registration requirements of the Securities Act. We offered and sold the notes in reliance on the exemption from registration provided by Section 4(2) of the Securities Act. The initial purchaser offered and sold the notes to "qualified institutional buyers" pursuant to the exemption from registration provided by Rule 144A under the Securities Act.

On October 18, 2011, we entered into warrant confirmation transactions with certain option counterparties relating to convertible note hedge and warrant transactions. Pursuant to the warrant confirmation transactions, up to 4,760,840 shares of our Common Stock (subject to adjustment from time to time as provided in the warrant confirmations) may be issuable upon the conversion of warrants. The strike price of the warrant transaction will initially be $103.41 per share. We offered and sold the warrants in reliance on the exemption from registration provided by Section 4(2) of the Securities Act. Neither the warrants nor the underlying shares of Common Stock issuable upon the conversion of the warrants have been registered under the Securities Act.

The net proceeds to us from the notes offering were approximately $391.3 million after deducting the initial purchaser's discount and estimated offering expenses. Although the gross proceeds to us from the sale of the warrants were approximately $93.8 million, we paid an aggregate of $117.5 million to the option counterparties for the convertible note hedge transactions. As a result, there were no additional net proceeds to us from the warrant transactions and we used $23.7 million of the net proceeds of the notes offering to fund the convertible hedge transactions. We intend to use the remaining net proceeds of the notes offering for general corporate purposes.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
10.1	- Eighth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 1, 2011.
10.2	- Ninth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 30, 2011.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	- Interactive Data File
101.INS	- XBRL Instance Document
101.SCH	- XBRL Taxonomy Extension Schema
101.CAL	- XBRL Taxonomy Extension Calculation Linkbase
101.LAB	- XBRL Taxonomy Extension Label Linkbase
101.PRE	- XBRL Taxonomy Extension Presentation Linkbase
101.DEF	- XBRL Taxonomy Extension Definition Document

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: October 27, 2011

By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

Exhibit 10.1

EIGHTH AMENDMENT TO LEASE

THIS EIGHTH AMENDMENT TO LEASE (this "Eighth Amendment") is entered into as of this 1st day of August, 2011 (the "Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment"), that certain Third Amendment to Lease dated as of April 29, 2009 (the "Third Amendment"), that certain Fourth Amendment to Lease dated as of December 3, 2009 (the "Fourth Amendment"), that certain Fifth Amendment to Lease dated as of February 11, 2010 (the "Fifth Amendment"), that certain Sixth Amendment to Lease dated as of June 4, 2010 (the "Sixth Amendment"), and that certain Seventh Amendment to Lease dated as of December 22, 2010 (the "Seventh Amendment" and, collectively with the Original Lease and the First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment and Sixth Amendment, and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 755, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings", and each a "Building");

B. WHEREAS, Landlord and Tenant are parties to that certain Space License Agreement ("Space License") dated as of the December 3, 2009 whereby Tenant licenses from Landlord approximately Six Thousand Five Hundred Sixty-Eight (6,568) square feet of Rentable Area on the S-Level of the building located at 777 Old Saw Mill River Road in Tarrytown, New York (the "777 License Area Premises");

C. WHEREAS, Tenant desires to exercise the option set forth in Article 25 of the Space License to lease from Landlord the 777 License Area Premises, as shown on Exhibit A attached hereto, and Landlord desires to lease to Tenant the 777 License Area Premises;

D. WHEREAS, Tenant desires to lease from Landlord and Landlord desires to lease to Tenant approximately Four Hundred Forty-Nine (449) square feet of Rentable Area on the third (3rd) floor of the building located at 765 Old Saw Mill River Road in Tarrytown, New York, as shown on Exhibit B attached hereto (the "765 Elevator Lobby Premises"); and

E. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Eighth Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Eighth Amendment, is referred to herein as the "Amended Lease."

2. Additions to Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the following space on the following terms:

(a) the 777 License Area Premises, effective as of the Execution Date. The parties acknowledge that Tenant has been licensing the 777 License Area Premises pursuant to the Space License. Effective as of the Execution Date, the 777 License Area Premises shall be included in the Amended Lease as a part of the Premises and the 777 License Area Premises shall be governed in all respects by the Amended Lease. The Term for the 777 License Area Premises shall expire on the Term Expiration Date for the New Premises, subject to (i) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease and (ii) Tenant's termination option set forth in Section 5(a) below. Commencing as of the date Landlord delivers the 777 License Area Premises to Tenant and continuing through the Term, and subject to the provisions of Section 5 hereof, Tenant shall pay to Landlord Basic Annual Rent for the 777 License Area Premises at an initial rate equal to Thirty-Four and 85/100 Dollars ($34.85) per square foot of Rentable Area per year in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 777 License Area Premises shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2012. In addition to Basic Annual Rent, commencing as of the date that Landlord delivers the 777 License Area Premises to Tenant, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the 777 License Area Premises. For the avoidance of doubt, HVAC for the 777 License Area Premises shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and the 777 License Area Premises shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the Term commencement date for the 777 License Area Premises); and

(b) the 765 Elevator Lobby Premises, effective as of the "765 Elevator Lobby Premises Commencement Date," which shall be the earlier of (i) fifteen (15) business days following the Execution Date and (ii) the date that Tenant completes construction of a demising wall ("Demising Wall"), in approximately the location depicted in Exhibit B, at Tenant's sole cost and expense. No construction management fee shall be paid to Landlord based upon the cost of installing the Demising Wall. The Term for the 765 Elevator Lobby Premises shall expire on the Term Expiration Date for the New Premises, subject to (A) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, (B) Tenant's termination option set forth in Section 5(b) below and (C) the provisions of Section 5(d) below. Commencing as of the 765 Elevator Lobby Premises Commencement Date and continuing through the Term, and subject to the provisions of Section 5 hereof, Tenant shall pay to Landlord Basic Annual Rent for the 765 Elevator Lobby Premises at an initial rate equal to Five and 00/100 Dollars ($5.00) per square foot of Rentable Area per year in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 765 Elevator Lobby Premises shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2012. In addition to Basic Annual Rent, commencing as of the 765 Elevator Lobby Premises Commencement Date, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the 765 Elevator Lobby Premises. For the avoidance of doubt, HVAC for the 765 Elevator Lobby Premises shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and the 765 Elevator Lobby Premises shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the 765 Elevator Lobby Premises Commencement Date).

3. Tenant's Pro Rata Shares. From and after (a) the Execution Date, with respect to the 777 License Area Premises, and (b) the 765 Elevator Lobby Premises Commencement Date with respect to the 765 Elevator Lobby Premises, the Premises shall thereafter be deemed to include the premises so delivered and Tenant's Pro Rata Shares of the Building, Existing Project, New Project and Entire Project shall be incrementally increased by the amounts set forth in Exhibit C attached hereto. As of each such date, the defined terms in Section 2.2 of the Lease shall be automatically amended to reflect the adjustments set forth in this Section. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under the Amended Lease, including pursuant to Section 9.2.

4. Parking. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces with respect to each portion of the Premises leased to Tenant hereunder.

5. Termination Options.

(a) Tenant shall be entitled to terminate the Lease with respect to the 777 License Area Premises on June 30, 2014, December 31, 2015, or December 31, 2016; provided that (x) Tenant provides Landlord with no less than eighteen (18) months' prior written notice and (y) on or before the date of such termination, Tenant pays to Landlord an amount equal to, if terminated on (i) June 30, 2014, One Hundred Ninety-Three Thousand Four Hundred Twenty-Seven and 60/100 Dollars ($193,427.60) (based on Twenty-Nine and 45/100 Dollars ($29.45) per square foot of Rentable Area of the applicable portion of the Premises), (ii) December 31, 2015, One Hundred Thirty-One Thousand Four Hundred Ninety-One and 36/100 Dollars ($131,491.36)(based on Twenty and 02/100 Dollars ($20.02) per square foot of Rentable Area of the applicable portion of the Premises), and (iii) December 31, 2016, Sixty-Eight Thousand Nine Hundred Sixty-Four and 00/100 Dollars ($68,964.00)(based on Ten and 50/100 Dollars ($10.50) per square foot of Rentable Area of the applicable portion of the Premises). If Tenant timely exercises its option to terminate the Lease with respect to the 777 License Area Premises, then Tenant shall surrender the 777 License Area Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration.

(b) Tenant shall be entitled to terminate the Lease with respect to the 765 Elevator Lobby Premises on June 30, 2014, December 31, 2015, or December 31, 2016; provided that Tenant provides Landlord with no less than eighteen (18) months' prior written notice. If Tenant timely exercises its option to terminate the Lease with respect to the 765 Elevator Lobby Premises or Tenant's lease of the 765 Elevator Lobby Premises expires or is terminated early, then Tenant shall surrender the 765 Elevator Lobby Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon expiration.

(c) Time is of the essence with respect to the exercise of the termination options granted in this Section 5.

(d) In the event that (i) Tenant exercises its Quad I and II Termination Option as set forth in Section 13(b) of the Third Amendment or (ii) Tenant's lease of any portion of the Quad I or Quad II Premises (as defined in the Third Amendment) expires or is terminated early (each of (i) and (ii), a "Quad I and II Premises Termination" and, collectively, "Quad I and II Premises Terminations"), then Tenant's lease of the 765 Elevator Lobby Premises shall also terminate effective as of the date of such Quad I and II Premises Termination(s). Upon termination of the 765 Elevator Lobby Premises due to a Quad I and II Premises Termination(s), the 765 Elevator Lobby Premises shall be considered a Common Area under the Amended Lease and shall no longer be included as part of Tenant's Pro Rata Share.

6. Lease Extension Options. From and after the Execution Date, the first paragraph of Article 44 of the Lease is hereby deleted and replaced with the following:

> 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises plus the Corridor Space, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises, (e) the Swap Premises and 765 Elevator Lobby Premises, (f) each full floor of the 755 Premises, (g) the 765 Expansion Premises, (h) the 765 Expansion Premises II, (i) C-Level Storage Spaces and (j) the 777 License Area Premises. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

7. Condition of Premises. Except as otherwise provided herein (including Section 2 hereof), Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the 777 License Area Premises or the 765 Elevator Lobby Premises with respect to the suitability of the same for the conduct of Tenant's business. Tenant acknowledges that it is generally familiar with the condition of the 777 License Area Premises and the 765 Elevator Lobby Premises and, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the same in its condition "as is" as of the applicable delivery date. Tenant's taking possession of the 777 License Area Premises and the 765 Elevator Lobby Premises, except as otherwise agreed to in writing by Landlord and Tenant, shall conclusively establish that the same were at such time in good, sanitary and satisfactory condition and repair. Notwithstanding the foregoing, Landlord represents and warrants that the Building Systems (including the HVAC systems) in the 777 License Area Premises and the 765 Elevator Lobby Premises are, and will be, in good working condition and that the same are, subject to the provisions of Section 17 of the Original Lease, currently serviced by Utilities and other base building services. Subject to Landlord's reasonable prior approval, Tenant shall have the right, at its sole cost and expense, to convert the Johnson Controls building controls serving the 777 License Area Premises and the 765 Elevator Lobby Premises from Landlord's network to Tenant's network.

8. Alterations. At Tenant's sole cost and expense, Tenant shall be permitted to install a card reader on the freight elevator serving the 765 Elevator Lobby Premises ("Card Reader"). No construction management fee shall be paid to Landlord based upon the cost of installing the Card Reader. At Landlord's request, Tenant shall remove the Card Reader upon the expiration or earlier termination of the Lease and shall promptly repair any damage caused thereby.

9. Termination of Space License. Landlord and Tenant acknowledge that, concurrent with the execution and delivery of this Eighth Amendment, Landlord and Tenant are executing the Space License Termination Agreement attached hereto as Exhibit D.

10. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Eighth Amendment, other than Studley ("Broker"), and agrees to indemnify, defend and hold Landlord harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with the making of this Eighth Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker.

11. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder.

12. Effect of Amendment. Except as modified by this Eighth Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Eighth Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Eighth Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Eighth Amendment.

13. Miscellaneous. This Eighth Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Eighth Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

14. Counterparts. This Eighth Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Eighth Amendment.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC,
a Delaware limited liability company

By: /s/ Kevin M. Simonsen
Name: Kevin M. Simonsen
Title: VP, Real Estate Counsel

TENANT:

REGENERON PHARMACEUTICALS, INC.,
a New York corporation

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

777 LICENSE AREA PREMISES

[IMAGE]

A-1

EXHIBIT B

765 ELEVATOR LOBBY PREMISES AND DEMISING WALL

[IMAGE]

B-1

EXHIBIT C

TENANT'S PRO RATA SHARES

Definition or Provision	**Means the Following:**	**Square Feet of Rentable Area**	**Tenant's Pro Rata Share of Applicable Building**	**Tenant's Pro Rata Share of Existing Project (827,790)**	**Tenant's Pro Rata Share of the Entire Project (1,188,310)**
Portion of added "Premises" and corresponding Rentable Area	777 License Area Premises	6,568	1.80%	0.79%	0.55%
	765 Elevator Lobby Premises	449	0.22%	0.05%	0.04%

EXHIBIT D

SPACE LICENSE TERMINATION AGREEMENT

[IMAGE]

D-1

SPACE LICENSE TERMINATION AGREEMENT

THIS SPACE LICENSE TERMINATION AGREEMENT (this "Agreement") is entered into as of this 1st day of August, 2011 ("Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Owner"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("User").

RECITALS

F. WHEREAS, Owner and User entered into that certain Space License Agreement ("Space License") dated as of the December 3, 2009 whereby User licenses from Owner approximately Six Thousand Five Hundred Sixty-Eight (6,568) square feet of rentable area on the S-Level of the building located at 777 Old Saw Mill River Road in Tarrytown, New York (the "License Area");

G. WHEREAS, the Term of the Space License continues through August 31, 2011;

H. WHEREAS, User desires to lease the License Area pursuant to an amendment to the Original Lease (as defined in the Space License); and

I. WHEREAS, Owner and User desire to terminate the Space License in accordance with the following provisions.

AGREEMENT

NOW, THEREFORE, Owner and User, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Termination of Space License Agreement. The parties hereby terminate the Space License as of the Execution Date, and on the Execution Date the Space License shall be fully and finally surrendered and terminated and shall no longer be of any force or effect, except for those provisions that, by their express terms, survive the expiration or earlier termination thereof.

2. Representation of Parties. Each party represents that it has not made any assignment, sublease, transfer, conveyance or other disposition of the Space License or any interest therein, nor made or entered into any agreement that would result in any mechanic's lien or other claim, demand, obligation, liability, action or cause of action arising from or with respect to the Space License or the License Area.

3. Miscellaneous.

a. Voluntary Agreement. The parties have read this Agreement and have freely and voluntarily entered into this Agreement.