10-Q 1 regeneron_10q.htm QUARTERLY REPORT

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<br>(State or other jurisdiction of incorporation or organization) | 13-3444607<br>(I.R.S. Employer Identification No.) |
| 777 Old Saw Mill River Road<br>Tarrytown, New York<br>(Address of principal executive offices) | 10591-6707<br>(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 __ |



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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 |

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**REGENERON PHARMACEUTICALS, INC.**
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**PART I. FINANCIAL INFORMATION**
**ITEM 1. FINANCIAL STATEMENTS**



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**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.**



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**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)**



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**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 | | 1,391 | | | 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 | $ 1,323,432 | $ (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 | | |



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| | | |
|---|---|---|
| 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.**



**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, 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



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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.



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**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,



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| | 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



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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.

| At September 30, 2009 | Amortized Cost Basis | Fair Value | Unrealized Gains | Unrealized (Losses) | Unrealized 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 |



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| | | | | | |
|---|---|---|---|---|---|
| | 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 | | |
|---|---|---|---|
| | Quoted Prices in Active Markets | Significant Other | Significant |



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| Description | Fair Value at September 30, 2009 | for Identical Assets (Level 1) | Observable Inputs (Level 2) | 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



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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 |



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**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



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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 |



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| | | | |
|---|---|---|---|
| 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***



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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.



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**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.



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**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**



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*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.



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**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.



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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 2$^{nd}$ 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 2$^{nd}$ line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The third trial (VENICE) is evaluating aflibercept as a 1$^{st}$ 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 1$^{st}$ line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin.



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In September 2009, as previously reported, a fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1$^{st}$ 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



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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.



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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



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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 Infitration 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.



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***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



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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.



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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.



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***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.



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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.



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**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.



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**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.



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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



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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<br>• 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<br>• Achieved more than 80% enrollment in each of the Phase 3 studies<br>• Reported results of a Phase 2 single-agent study in symptomatic malignant ascites (SMA)<br>• 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<br>• 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)<br>• Completed enrollment of patients in the Phase 2 DME trial<br>• Initiated a Phase 3 CRVO program | • Continue enrollment in Phase 3 CRVO trials<br>• Report data from Phase 2 DME trial during the first half of 2010<br>• 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<br>• Initiated a Phase 1 trial for REGN421(anti-Dll4) in oncology<br>• 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<br>• Initiate a dose-ranging study for REGN88 in rheumatoid arthritis<br>• Initiate additional Phase 2 trials for REGN475 in pain indications<br>• Report data from the study of REGN475 in osteoarthritis of the knee during the first half of 2010<br>• Advance additional antibody candidate(s) into clinical development |



**Results of Operations**



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***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



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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:



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| Expenses (In millions) | For the three months ended September 30, 2009 | | |
|---|---|---|---|
| | 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 |

| Expenses (In millions) | For the three months ended September 30, 2008 | | |
|---|---|---|---|
| | 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 (In millions) | For the three months ended September 30, 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.



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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.



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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.



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***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:*



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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.



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| 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:

| Expenses | For the nine months ended September 30, 2009 | | |
|---|---|---|---|
| *(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 |

| Expenses | For the nine months ended September 30, 2008 | | |
|---|---|---|---|
| | Expenses before inclusion of Non-cash Compensation | Non-cash Compensation | Expenses as |



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| *(In millions)* | Expense | Expense | 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



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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*:



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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 |



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| | | | |
|---|---|---|---|
| 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.



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***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** |



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| | | | | |
|---|---|---|---|---|
| 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:***



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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.



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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



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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



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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.



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**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.



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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



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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.



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***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



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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.



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***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.



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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.



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**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



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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.



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***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



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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.



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***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.



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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.



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**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



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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



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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.



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***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.***



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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.



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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.



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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.



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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.***



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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.



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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:



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- 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



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| 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)





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