Exhibit 99.1

For Immediate Release

Press Release

Regeneron Reports First Quarter 2009 Financial and Operating Results

Tarrytown, New York (April 30, 2009) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the first quarter 2009. The Company reported a net loss of $17.5 million, or $0.22 per share (basic and diluted), for the first quarter of 2009 compared with a net loss of $11.6 million, or $0.15 per share (basic and diluted), for the first quarter of 2008.

At March 31, 2009, cash, restricted cash, and marketable securities totaled $496.0 million compared with $527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST® (rilonacept) – Inflammatory Diseases

The Company shipped $4.3 million of ARCALYST®(rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the first quarter of 2009, compared to $0.8 million during the first quarter of 2008. Shipments of ARCALYST began in the United States in March 2008 following marketing approval of ARCALYST from the U.S. Food and Drug Administration (FDA) in February 2008 for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. ARCALYST, an interleukin-1 (IL-1) blocker, is the only therapy approved in the United States for patients with CAPS. The Company currently projects shipments of ARCALYST to its distributors to total approximately $15-20 million in 2009.

During the first quarter of 2009, the Company initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, three of which are currently enrolling patients: Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 program also includes a separate placebo-controlled safety study (RE-SURGE). The Company expects to report initial data from the Phase 3 program in 2010. Regeneron owns worldwide rights to ARCALYST.

Aflibercept (VEGF Trap) – Oncology

At the end of the first quarter of 2009, approximately one-half of the planned number of patients were enrolled in four Phase 3 trials that are evaluating combinations of aflibercept, an investigational anti-angiogenesis agent, with standard chemotherapy regimens for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VANILLA) is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine. A third trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The fourth trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. Initial data from the Phase 3 program are expected in 2010. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin began recruiting patients in January 2009.

A Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA) is now fully enrolled, and initial data from this trial are expected by mid-2009. Aflibercept is being developed worldwide by Regeneron and its collaborator, sanofi-aventis.

VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications that is being developed by Regeneron and its collaborator, Bayer HealthCare, for the treatment of the neovascular form of Age-related Macular Degeneration (wet AMD), Diabetic Macular Edema (DME), Central Retinal Vein Occlusion (CRVO), and other eye diseases and disorders.

In a separate news release today, Regeneron and Bayer HealthCare announced plans to initiate a Phase 3 program later this year of VEGF Trap-Eye in the treatment of CRVO. Dosing of the first patient in the Phase 3 program will entitle Regeneron to receive a $20.0 million milestone payment.

The Phase 3 program (consisting of the VIEW 1 and VIEW 2 studies) that is evaluating VEGF Trap-Eye in patients with wet AMD continued to enroll patients during the first quarter of 2009. The companies expect to complete enrollment in both trials in 2009 and report initial data in late 2010.

Results of the extension stage of the Phase 2 study in wet AMD (the CLEAR-IT 2 study) will be presented on May 4 at the 2009 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida. In late 2008, the companies reported CLEAR-IT 2 study results, which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year.

In the original Phase 2 study, 157 patients were initially treated for 3 months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial 3-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

The data to be presented at ARVO will report on 117 patients who elected to enter the extension stage of the study after receiving VEGF Trap-Eye for one year. These patients were dosed on a 2.0 mg PRN basis. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters ($p<0.0001$ versus baseline) at the 3-month primary endpoint of the original Phase 2 study, 8.4 letters ($p<0.0001$ versus baseline) at one year, and 7.1 letters ($p<0.0001$ versus baseline) at month 6 of the extension stage. Thus, after 18 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 3.5 injections over the 15-month PRN dosing phase that extended from month 3 to month 18. Patients continue to be dosed in the extension stage of the Phase 2 study.

Among all the patients in the Phase 2 wet AMD study, VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and two arterial thrombotic events; these were deemed not to be drug-related. Three deaths were reported—one patient with pancreatic cancer, one patient with squamous cell carcinoma of the lung, and one patient with pulmonary hypertension (a pre-existing condition), The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

In the Phase 2 DME study, additional clinical sites were opened during the first quarter of 2009. The study (called DA VINCI) is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study began in December 2008 and is expected to complete enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia by the end of 2009.

Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

Monoclonal Antibodies

Phase 1 clinical studies have begun with the first three human monoclonal antibodies generated by Regeneron using its *VelocImmune®* technology. REGN88 is an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis. REGN475, an antibody to Nerve Growth Factor (NGF) that binds NGF selectively without cross-reacting with other members of the neurotrophin family, is being developed for the treatment of pain. In addition, a Phase 1 trial is in the process of being initiated to evaluate REGN421, an antibody to Delta-like ligand-4 (Dll4), in patients with advanced malignancies. These antibodies are being developed within the Company's human antibody collaboration with sanofi-aventis. Over the course of the next several years, the Company and sanofi-aventis plan to advance an average of two to three new fully human monoclonal antibodies into clinical development each year.

As part of its Academic *VelocImmune* Investigators' Program (Academic VIP), during the first quarter of 2009 Regeneron entered into an agreement with The University of Texas Southwestern Medical Center that will provide researchers at the Dallas-based medical center with access to Regeneron's *VelocImmune* technology to discover fully human monoclonal antibodies. Regeneron retains the right to develop and commercialize any antibodies discovered under the program.

Financial Results

Revenues

Total revenues increased to $75.0 million in the first quarter of 2009 from $56.4 million in the same period of 2008. The Company's revenue was comprised of contract research and development revenue, technology licensing revenue, and net product sales.

Contract Research and Development Revenue

Contract research and development revenue relates primarily to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Contract research and development revenue for the three months ended March 31, 2009 and 2008 consisted of the following:

	Three months ended March 31,	
(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis	$ 49.6	$ 35.7
Bayer HealthCare	10.0	9.0
Other	1.5	1.7
Total contract research & development revenue	$ 61.1	$ 46.4

For the three months ended March 31, 2009 and 2008, contract research and development revenue from sanofi-aventis consisted of the following:

	Three months ended March 31,	
(In millions)	2009	2008
Aflibercept:		
Regeneron expense reimbursement	$ 5.4	$ 11.7
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total aflibercept	7.9	13.8
Antibody:		
Regeneron expense reimbursement	38.4	19.3
Recognition of deferred revenue related to up-front payment	2.6	2.6
Other	0.7	
Total antibody	41.7	21.9
Total sanofi-aventis contract research & development revenue	$ 49.6	$ 35.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first quarter of 2009, compared to the same period in 2008, primarily due to lower costs associated with manufacturing clinical drug supplies.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased in the first quarter of 2009, compared to the same period in 2008, due to an increase in research activities conducted under the collaboration's discovery agreement and increases in development activities for REGN88, REGN421, and REGN475 under the collaboration's license agreement.

For the three months ended March 31, 2009 and 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended March 31,	
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 7.5	$ 5.7
Recognition of deferred revenue related to up-front and milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	$ 10.0	$ 9.0

In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration with Bayer HealthCare, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. The Company incurred higher VEGF Trap-Eye development expenses under the collaboration for the three months ended March 31, 2009, compared to the same period in 2008, primarily in connection with the collaboration's clinical development programs in wet AMD and DME.

Technology Licensing Revenue

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune®* technology in their internal research programs to discover human monoclonal antibodies. Each company is required to make six $20.0 million annual, non-refundable payments, subject to the ability to terminate their agreements after making a total of four such payments. To date, the Company has received $60.0 million in payments from AstraZeneca and $40.0 million in payments from Astellas under these agreements. Upon receipt, these payments are deferred and recognized as revenue ratably over the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*.

Net Product Sales
Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. For the three months ended March 31, 2009, the Company recognized as revenue $3.9 million of ARCALYST® (rilonacept) net product sales for which the right of return no longer exists and rebates can be reasonably estimated. At March 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $4.2 million and $0.8 million, respectively.

Expenses
Total operating expenses for the first quarter of 2009 were $94.2 million, 30 percent higher than the same period in 2008. Average headcount increased to 938 for the first quarter of 2009 compared to 714 for the same period in 2008, due primarily to the Company's expanding research and development activities principally in connection with the sanofi-aventis antibody collaboration. Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of $7.7 million and $8.3 million, in the first quarters of 2009 and 2008, respectively.

Research and development (R&D) expenses increased to $82.1 million in the first quarter of 2009 from $61.3 million in the comparable quarter of 2008. In the first quarter of 2009, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for ARCALYST, VEGF Trap-Eye, and REGN88, research and preclinical development costs associated with the antibody programs, and facility-related costs to support expanded R&D activities.

Selling, general, and administrative (SG&A) expenses increased to $11.7 million in the first quarter of 2009 from $11.0 million in the comparable quarter of 2008. In the first quarter of 2009, the Company incurred higher selling expenses related to ARCALYST® (rilonacept), higher compensation expense associated with expanding the Company's SG&A headcount, and higher SG&A facility-related costs.

Other Income and Expense
Investment income decreased to $1.8 million in the first quarter of 2009 from $7.3 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter in 2008. Interest expense in the first quarter of 2008 was attributable to the Company's 5.5% Convertible Senior Subordinated Notes; no Notes were outstanding in 2009.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2008. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2009	December 31, 2008
ASSETS		
Cash, restricted cash, and marketable securities	$ 495,992	$ 527,461
Receivables	48,209	35,212
Property, plant, and equipment, net	109,840	87,853
Other assets	27,380	19,512
Total assets	$ 681,421	$ 670,038
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 44,832	$ 36,168
Deferred revenue	213,119	209,925
Other liabilities	13,150	5,093
Stockholders' equity	410,320	418,852
Total liabilities and stockholders' equity	$ 681,421	$ 670,038

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended March 31,	
	2009	2008
Revenues		
Contract research and development	$ 61,090	$ 46,383
Technology licensing	10,000	10,000
Net product sales	3,891	
	74,981	56,383
Expenses		
Research and development	82,146	61,270
Selling, general, and administrative	11,674	11,024
Cost of goods sold	392	
	94,212	72,294
Loss from operations	(19,231)	(15,911)
Other income (expense)		
Investment income	1,750	7,304
Interest expense		(3,011)
	1,750	4,293
Net loss	$ (17,481)	$ (11,618)
Net loss per share amounts, basic and diluted	$ (0.22)	$ (0.15)
Weighted average shares outstanding, basic and diluted	79,498	78,493

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 11/4/2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 2009 (November 3, 2009)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	000-19034	13-3444607
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2009, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2009. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 3, 2009.

SIGNATURES

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 hereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: November 4, 2009

By: /s/ Stuart Kolinski
Name: Stuart Kolinski
Title: Senior Vice President and General Counsel

Exhibit Index

Number	Description
99.1	Press Release dated November 3, 2009.

REGENERON

Exhibit 99.1

For Immediate Release

Press Release

Regeneron Reports Third Quarter 2009 Financial and Operating Results

Tarrytown, New York (November 3, 2009) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the third quarter of 2009. The Company reported a net loss of $1.0 million, or $0.01 per share (basic and diluted), for the third quarter of 2009 compared with a net loss of $19.1 million, or $0.24 per share (basic and diluted), for the third quarter of 2008. The Company reported a net loss of $31.3 million, or $0.39 per share (basic and diluted), for the nine months ended September 30, 2009 compared with a net loss of $49.6 million, or $0.63 per share (basic and diluted), for the same period in 2008. During the third quarter of 2009, the Company recognized as revenue a $20.0 million milestone payment from Bayer HealthCare, as described below.

At September 30, 2009, cash, restricted cash, and marketable securities totaled $438.6 million compared with $527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST® (rilonacept) – Inflammatory Diseases

The Company shipped $5.3 million of ARCALYST® (rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the third quarter of 2009, compared to $4.3 million in the same quarter of 2008. Shipments during the first nine months of 2009 were $15.0 million compared to $6.7 million for the same period of 2008. ARCALYST, an interleukin-1 (IL-1) blocker, was approved in the United States in February 2008 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. The Company currently projects shipments of ARCALYST to its U.S. distributors to total approximately $20 million in 2009. 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.

ARCALYST is in a Phase 3 clinical development program 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). The Company expects to report initial data from the Phase 3 program in the first half of 2010. Regeneron owns worldwide rights to ARCALYST (rilonacept).

Aflibercept (VEGF Trap) – Oncology

Aflibercept, an anti-angiogenic protein product candidate designed to bind all forms of vascular endothelial growth factor A (VEGF-A), is being developed worldwide by Regeneron and its collaborator, sanofi-aventis. At the end of the third quarter of 2009, more than 80 percent of the planned number of patients were enrolled in each of three Phase 3 trials that are evaluating combinations of aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. 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 the current enrollment and number of events, 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, a Phase 2 study (AFFIRM) is being conducted of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin.

In September 2009, as previously reported, a fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC. As part of a planned interim efficacy analysis, the Committee 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.

VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye, a specially purified and formulated form of VEGF Trap for use in intraocular treatment of retinal disease, is being developed by Regeneron and its collaborator, Bayer HealthCare. Two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye in patients with the neovascular form of Age-related Macular Degeneration (wet AMD) are now fully enrolled, and we expect initial data from this program to be reported in late 2010. A Phase 2 study (called DA VINCI) of VEGF Trap-Eye for the treatment of the Diabetic Macular Edema (DME) is also fully enrolled, with data expected during the first half of 2010. Additionally, two Phase 3 studies in Central Retinal Vein Occlusion (CRVO) are enrolling patients; data from the first of these studies are anticipated to be available in the first half of 2011.

During October 2009, 24-month results of the extension stage of the Phase 2 study of VEGF Trap-Eye in wet AMD (CLEAR-IT 2) were presented 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 study. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injection.

Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

Monoclonal Antibodies

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. REGN475, REGN88, and REGN421 are fully human monoclonal antibodies generated by Regeneron using the *VelocImmune®* technology and developed within the Company's human antibody collaboration with sanofi-aventis. Regeneron 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 next several years.

Financial Results

Revenues

Total revenues increased to $117.5 million in the third quarter of 2009 from $65.6 million in the same quarter of 2008 and increased to $282.5 million for the first nine months of 2009 from $182.6 million for the same period of 2008. The Company's revenue was comprised of contract research and development revenue, a 2009 research progress payment, technology licensing revenue, and net product sales.

Contract Research and Development Revenue

Contract research and development revenue relates primarily to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Contract research and development revenue for the three and nine months ended September 30, 2009 and 2008 consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Contract research & development revenue:				
Sanofi-aventis	$ 68.5	$ 42.0	$ 178.9	$ 116.3
Bayer HealthCare	12.2	9.0	34.9	28.2
Other	1.8	1.9	5.3	5.4
Total contract research & development revenue	$ 82.5	$ 52.9	$ 219.1	$ 149.9

For the three and nine months ended September 30, 2009 and 2008, contract research and development revenue from sanofi-aventis consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Aflibercept:				
Regeneron expense reimbursement	$ 7.0	$ 7.3	$ 21.6	$ 29.3
Recognition of deferred revenue related to up-front payments	2.5	2.1	7.4	6.2
Total aflibercept	9.5	9.4	29.0	35.5
Antibody:				
Regeneron expense reimbursement	55.7	29.5	139.8	72.4
Recognition of deferred revenue related to up-front payment	2.6	2.6	7.9	7.9
Recognition of revenue related to *VelociGene®* agreement	0.7	0.5	2.2	0.5
Total antibody	59.0	32.6	149.9	80.8
Total sanofi-aventis contract research & development revenue	$ 68.5	$ 42.0	$ 178.9	$ 116.3

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three and nine months ended September 30, 2009, compared to the same periods in 2008, primarily due to lower Company costs associated with internal research activities and, for the nine months ended September 30, 2009, lower costs related to manufacturing clinical drug supplies. Sanofi-aventis also incurs aflibercept development expenses directly, including costs related to the Phase 3 clinical trials sanofi-aventis is overseeing in the oncology program.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased for the three and nine months ended September 30, 2009, compared to the same periods in 2008, due to an increase in research activities conducted under the collaboration's discovery agreement and increases in development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the collaboration's license agreement.

For the three and nine months ended September 30, 2009 and 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 9.7	$ 5.7	$ 27.5	$ 18.3
Recognition of deferred revenue related to up-front and non-substantive milestone payments	2.5	3.3	7.4	9.9
Total Bayer HealthCare contract research & development revenue	$ 12.2	$ 9.0	$ 34.9	$ 28.2

In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration with Bayer HealthCare, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. The Company incurred higher VEGF Trap-Eye development expenses under the collaboration for the three and nine months ended September 30, 2009, compared to the same period in 2008, primarily in connection with the collaboration's clinical development programs in wet AMD, DME, and CRVO.

Research Progress Payment
In July 2009, the Company 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 and nine months ended September 30, 2009.

Technology Licensing Revenue
Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune®* technology in their internal research programs to discover human monoclonal antibodies. Each company is required to make six $20.0 million annual, non-refundable payments, subject to the ability to terminate their agreements after making a total of four such payments. To date, the Company has received $60.0 million in payments from each of AstraZeneca and Astellas under these agreements. Upon receipt, these payments are deferred and recognized as revenue ratably over the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*.

Net Product Sales
Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. For the three and nine months ended September 30, 2009, the Company recognized as revenue $5.0 million and $13.4 million of ARCALYST® (rilonacept) net product sales, respectively, for which the right of return no longer exists and rebates can be reasonably estimated, compared to $2.7 million for 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.

Expenses
Total operating expenses for the third quarter of 2009 were $118.7 million, 42 percent higher than the same period in 2008, and $317.2 million for the first nine months of 2009, 34 percent higher than the same period in 2008. Average headcount increased to 998 in the third quarter of 2009 from 851 in the same period of 2008 and increased to 967 for the first nine months of 2009 from 778 in the same period of 2008, due primarily to the Company's expanding research and development activities principally in connection with the sanofi-aventis antibody collaboration. Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of $7.5 million in the third quarter of 2009 and $22.6 million for the first nine months of 2009, compared with $8.2 million and $24.7 million, respectively, for the same periods of 2008.

Research and development (R&D) expenses increased to $105.4 million in the third quarter of 2009 from $72.1 million in the comparable quarter of 2008, and to $280.0 million in the first nine months of 2009 from $200.3 million in the same period of 2008. In the third quarter and first nine months of 2009, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for ARCALYST, VEGF Trap-Eye, and monoclonal antibodies, research and preclinical development costs associated with the antibody programs, and facility-related costs to support expanded R&D activities.

Selling, general, and administrative (SG&A) expenses increased to $12.8 million in the third quarter of 2009 from $11.1 million in the comparable quarter of 2008, and to $35.9 million in the first nine months of 2009 from $35.7 million in the same period of 2008. In the third quarter and for the first nine months of 2009, the Company incurred higher compensation and facility-related expenses due primarily to increases in administrative headcount to support the expanded research and development activities, higher patent-related costs, and higher expenses related to ARCALYST® (rilonacept), partially offset by lower market research costs related to various programs and a decrease in recruitment costs for administrative headcount.

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 and to $3.9 million in the first nine months of 2009 compared to $15.5 million in the first nine months of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in 2009 compared to 2008.

Interest expense decreased to $0.6 million in the third quarter of 2009 from $1.8 million in the comparable quarter of 2008, and to $0.6 million in the first nine months of 2009 from $7.5 million in the same period of 2008. Interest expense in 2009 was attributable to the imputed interest portion of the Company's payments to its landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York, which commenced in the third quarter of 2009. Interest expense in 2008 was attributable to the Company's 5.5 percent Convertible Senior Subordinated Notes; no Notes were outstanding in 2009. During the first nine months of 2008, the Company repurchased $82.5 million in principal amount of its 5.5 percent Convertible Senior Subordinated Notes. In connection with the repurchased notes, the Company recognized a $0.9 million loss on early extinguishment of debt. The remaining $117.5 million of these notes were repaid in full upon their maturity in October 2008.

Income Tax Expense

In the third quarter of 2008, the Company incurred and paid income tax expense, consisting primarily of alternative minimum tax, of $3.1 million, which resulted from the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years.

Revision of Previously Issued Financial Statements

The Company has revised its financial statements at December 31, 2008 and for the three and nine months ended September 30, 2008 in connection with the application of authoritative guidance issued by the Financial Accounting Standards Board (FASB) to the Company's December 2006 lease, as amended, of laboratory and office facilities in Tarrytown, New York. The revisions consisted entirely of non-cash adjustments, primarily to the Company's balance sheet at December 31, 2008, and had no impact to the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the development of its product candidates. The revisions, and a description of the basis for the revisions, are more fully described in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2008 and Form 10-Q for the quarter ended September 30, 2009. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	September 30, 2009	December 31, 2008
		*(Revised)**
ASSETS		
Cash, restricted cash, and marketable securities	$ 438,596	$ 527,461
Receivables	67,766	35,212
Property, plant, and equipment, net	215,169	142,035
Other assets	20,661	19,512
Total assets	$ 742,192	$ 724,220
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 55,291	$ 36,168
Deferred revenue	198,546	209,925
Facility lease obligation	62,571	54,182
Other long-term liabilities	3,341	2,431
Stockholders' equity	422,443	421,514
Total liabilities and stockholders' equity	$ 742,192	$ 724,220

** Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."*

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2009	2008	2009	2008
		*(Revised)**		*(Revised)**
Revenues				
Contract research and development	$ 82,482	$ 52,878	$ 219,104	$ 149,914
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 amounts, 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

** Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."*

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Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 12/20/2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 20, 2010 (December 20, 2010)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On December 20, 2010, Regeneron Pharmaceuticals, Inc. ("Regeneron") and Bayer HealthCare issued a press release announcing results for VEGF Trap-Eye (aflibercept ophthalmic solution) in a Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in a Phase 2 Study in Diabetic Macular Edema (DME).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item. As noted during our investor teleconference on December 20, 2010, the attached press release inadvertently omitted certain information, which Regeneron does not consider to be material. To reflect inclusion of such omitted information, the sentence that reads "VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study" would be replaced with the following "In this study, VEGF Trap-Eye was generally well-tolerated and no patients experienced ocular drug-related serious adverse events. With respect to the number of patients with non-ocular serious adverse events judged by investigators to be drug-related, there were none during the first six months of the study and one in the second six months."

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010.

SIGNATURES

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 hereunto duly authorized.

Date: December 20, 2010

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

Number	Description
99.1	Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010

REGENERON

Exhibit 99.1

For Immediate Release

Press Release

Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME)

In Phase 3 study in CRVO, 56 percent of VEGF Trap-Eye patients gained at least 15 letters of vision compared to 12 percent in control group; VEGF Trap-Eye patients on average gained 17 letters of vision compared to mean loss of 4 letters in control group

In Phase 2 study in DME, patients in all VEGF Trap-Eye dose groups, including VEGF Trap-Eye dosed every two months, maintained or increased vision gains through 52-weeks

Regeneron to receive $20 million in milestone payments in connection with VEGF Trap-Eye program

Tarrytown, NY, USA, and Berlin, Germany, December 20, 2010 -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Bayer HealthCare today announced positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the COPERNICUS study, which is led by Regeneron, the first of two Phase 3 studies in patients with macular edema due to central retinal vein occlusion (CRVO). In this trial, 56.1 percent of patients receiving VEGF Trap-Eye 2 milligrams (mg) monthly gained at least 15 letters of vision from baseline, compared to 12.3 percent of patients receiving sham injections ($p<0.0001$), the primary endpoint of the study. Patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 17.3 letters of vision compared to a mean loss of 4.0 letters with sham injections ($p<0.001$), a secondary endpoint. The second Phase 3 study, GALILEO, is currently ongoing and is led by Bayer HealthCare.

VEGF Trap-Eye was generally well tolerated and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. A total of 114 patients were randomized to receive VEGF Trap-Eye and 73 patients to the control arm. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%) and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with VEGF Trap-Eye and two in the 73 (2.7%) patients treated with sham injections.

"In the COPERNICUS trial, patients treated with VEGF Trap-Eye experienced a marked improvement in vision," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "If these results are confirmed by data from the GALILEO study, expected in the second quarter of 2011, VEGF Trap-Eye could provide patients and physicians with a new treatment option for central retinal vein occlusion."

"After reporting positive results from our global Phase 3 program (VIEW 1 and VIEW 2 studies) for the treatment of the neovascular form of age related macular degeneration (wet AMD), we are pleased to also have a positive Phase 3 trial with VEGF Trap-Eye in central retinal vein occlusion, a potential second indication," said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. "We are working diligently with Regeneron to prepare regulatory filings for VEGF Trap-Eye in wet AMD to submit in the first half of 2011."

Detailed results for COPERNICUS will be presented at the Angiogenesis Conference in Miami, Florida in February 2011.

Regeneron will receive a $10 million milestone payment from Bayer HealthCare in connection with the COPERNICUS trial meeting its primary endpoint and received a $10 million milestone payment in December 2010 for the positive VIEW 1 and VIEW 2 trial results in wet AMD.

Phase 2 DME Results
Regeneron and Bayer HealthCare also reported 52 week follow-up results from the Phase 2 DA VINCI study in patients with diabetic macular edema (DME). In this study, the previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks (the primary endpoint of the study) were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including 2mg dosed every other month. Based on these positive results, Regeneron and Bayer HealthCare are discussing plans to initiate Phase 3 studies.

In this double-masked, prospective, randomized, multi-center Phase 2 trial, entitled **DA VINCI** (**D**ME **A**nd **V**EGF Trap-Eye: **IN**vestigation of **C**linical Impact), 221 patients with clinically significant DME with central macular involvement were randomized and 219 patients were treated with balanced distribution over five groups. The control group received macular laser therapy at baseline, and patients were eligible for repeat laser treatments, but no more frequently than at 16 week intervals. Two groups received monthly doses of 0.5 or 2mg of VEGF Trap-Eye throughout the 12-month dosing period. Two groups received three initial monthly doses of 2mg of VEGF Trap-Eye (at baseline and weeks 4 and 8), followed through week 52 by either every two months dosing or PRN (as-needed) dosing with very strict repeat dosing criteria. Mean gains in visual acuity versus baseline were as follows:

	Laser	0.5mg monthly	2mg monthly	2mg every two months*	2mg PRN*
n	44	44	44	42	45
Mean change in visual acuity at week 24 versus baseline[1] (letters)	2.5	8.6**	11.4**	8.5**	10.3**
Mean change in visual acuity at week 52 versus baseline (letters)	-1.3	11.0**	13.1**	9.7**	12.0**

*Following 3 initial monthly doses
**p<0.01 versus laser
[1] Primary endpoint

No significant differences among the VEGF Trap-Eye arms were observed. Approximately 80 percent of the VEGF Trap-Eye patients and 75 percent of the laser patients remained in the study through 52 weeks.

VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study. The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent ocular adverse events reported among patients receiving VEGF Trap-Eye included conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. The incidence of non-ocular serious adverse events was generally well balanced between all treatment arms. There were six deaths (3.4%) among the 175 patients treated with VEGF Trap-Eye and one (2.3%) in the 44 patients treated with laser over 12 months.

Detailed results for DA VINCI will be presented at the Angiogenesis Conference in Miami, Florida in February 2011.

About the Phase 3 CRVO Program
Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies receive six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections. Patients in the COPERNICUS trial were randomized in a 3:2 ratio with 114 patients randomized to receive VEGF Trap-Eye and 73 randomized to the control arm. At the end of the initial six months, all patients randomized to VEGF Trap-Eye are dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months are eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients are eligible for rescue laser treatment. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

About Central Retinal Vein Occlusion (CRVO)
Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

About Diabetic Macular Edema (DME)
DME is the most prevalent cause of moderate vision loss in patients with diabetes. DME is a common complication of Diabetic Retinopathy (DR), a disease affecting the blood vessels of the retina. Clinically significant DME is a leading cause of blindness in younger adults (under 50). Clinically significant DME occurs when fluid leaks into the center of the macula, the light-sensitive part of the retina responsible for sharp, direct vision. Fluid in the macula can cause severe vision loss or blindness.

Approximately 370,000 Americans currently suffer from clinically significant DME, with 95,000 new cases arising each year. According to the American Diabetes Association, more than 18 million Americans currently suffer from diabetes, and many other people are at risk for developing diabetes. With the incidence of diabetes steadily climbing, it is projected that up to 10 percent of all patients with diabetes will develop DME during their lifetime.

About VEGF Trap-Eye
VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), diabetic macular edema (DME), central retinal vein occlusion (CRVO), and other eye diseases and disorders. In November 2010, Regeneron and Bayer HealthCare announced positive top-line results from two parallel Phase 3 studies in patients with wet AMD, VIEW 1 and VIEW 2. In these trials, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint compared to the current standard of care, ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. A generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies. There were no notable differences in non-ocular adverse events among the study arms. Bayer HealthCare and Regeneron are planning to submit regulatory applications for marketing approval for the treatment of wet AMD in Europe and the U.S. in the first-half of 2011.

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. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 15.9 billion (2009), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 53.400 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Regeneron Forward Looking Statement
This news release includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Astellas, the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended September 30, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

Bayer Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 2/18/2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 17, 2011 (February 17, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On February 17, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and year ended December 31, 2010. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated February 17, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: February 17, 2011

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

Number	Description
99.1	Press Release dated February 17, 2011

Exhibit 99.1

REGENERON

For Immediate Release

Press Release

Regeneron Reports Full Year and Fourth Quarter 2010 Financial and Operating Results

Tarrytown, New York (February 17, 2011) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial results for the full year and fourth quarter of 2010 and provided an update on development programs and upcoming milestones.

"2010 was a very productive year for Regeneron as we reported positive Phase 3 results in four clinical trials: two with VEGF Trap-Eye in wet age-related macular degeneration, called wet AMD, one with VEGF Trap-Eye in central retinal vein occlusion, and one with ARCALYST® for the prevention of gout flares in patients initiating uric-acid lowering therapy," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We expect regulatory applications to be filed in the first half of 2011 for marketing approval in the U.S. and Europe for VEGF Trap-Eye in wet AMD. We also look forward to reporting results from additional Phase 3 trials in central retinal vein occlusion and gout and from two Phase 3 trials with aflibercept in cancer."

"In anticipation of potential product approvals," Dr. Schleifer added, "we are continuing to build our commercialization capabilities. We are also advancing our earlier-stage pipeline which currently includes eight fully-human monoclonal antibodies in clinical development for the treatment of various diseases and conditions including elevated LDL cholesterol, rheumatoid arthritis, atopic dermatitis, and cancer. We anticipate Phase 2 data from some of these programs in 2011."

"We entered 2011 in a strong financial position to support our development and commercialization activities," commented Murray A. Goldberg, Chief Financial Officer, "with approximately $627 million in cash and securities, following a successful public offering of Common Stock in October 2010."

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) – Ophthalmologic Diseases

VEGF Trap-Eye is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PLGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

Phase 3 studies in wet age-related macular degeneration

In November 2010, Regeneron and Bayer Healthcare reported positive one-year data from two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD). Based on these results, Regeneron plans to submit a Biologics License Application to the Food and Drug Administration (FDA) for marketing approval in the U.S. in the first half of 2011. In addition, Bayer Healthcare intends to submit regulatory applications in the first half of 2011 for marketing approval in Europe.

In VIEW 1 and VIEW 2, VEGF Trap-Eye was administered either monthly or every two months, and compared to monthly doses of ranibizumab, which is the current standard of care in wet AMD. In these studies, all regimens of VEGF Trap-Eye including VEGF Trap-Eye dosed every two months successfully met the primary endpoint of non-inferiority compared to ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. At least 94% of patients in every VEGF Trap-Eye group, including those dosed every two months, as well as those receiving ranibizumab dosed monthly, maintained visual acuity over 52 weeks. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity. Maintenance of vision was defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS eye chart.

In VIEW 1 and VIEW 2, a generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD.

Phase 3 studies in central retinal vein occlusion

In December 2010, Regeneron and Bayer Healthcare reported positive initial results from the COPERNICUS study, the first of two Phase 3 studies evaluating VEGF Trap-Eye in central retinal vein occlusion (CRVO). Patients received six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 milligrams (mg) or sham control injections. In COPERNICUS, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in vision at six months compared to sham injections. In this trial, 56.1% of patients receiving VEGF Trap-Eye gained at least 15 letters of vision from baseline, compared to 12.3% of patients receiving sham injections ($p<0.0001$). Patients receiving VEGF Trap-Eye on average gained 17.3 letters of vision, compared to a mean loss of 4.0 letters with sham injections ($p<0.001$), a secondary endpoint.

In the COPERNICUS study, VEGF Trap-Eye was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%) and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms.

Initial results from GALILEO, the second of the two Phase 3 studies in CRVO, are expected in the first half of 2011.

Phase 2 study in diabetic macular edema

In December 2010, Regeneron and Bayer Healthcare reported 52-week results from a Phase 2 study (DA VINCI) comparing treatment with VEGF Trap-Eye to focal laser therapy, the current standard of care, in patients with clinically significant diabetic macular edema (DME). The DME data showed that previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks, the primary endpoint of the study, were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including the group receiving a 2.0 mg dose every other month. At week 52, all VEGF Trap-Eye dose groups reported mean gains in visual acuity of 9.7 to 13.1 letters, compared to a mean loss of 1.3 letters for patients receiving focal laser therapy ($p<0.01$ for each VEGF Trap-Eye group versus focal laser).

In DA VINCI, VEGF Trap-Eye was generally well tolerated. The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent ocular adverse events reported among patients receiving VEGF Trap-Eye included conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. There were no non-ocular serious adverse events judged by investigators to be drug-related during the first six months of the study and one during the second six months.

Based on these positive results, Regeneron and Bayer Healthcare are discussing plans to initiate Phase 3 studies of VEGF Trap-Eye in DME.

Phase 3 study in choroidal neovascularisation

In January 2011, Regeneron and Bayer HealthCare announced a new Phase 3 clinical trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye in patients with choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia.

ARCALYST® (rilonacept) – Gout

ARCALYST® is a fusion protein that blocks the cytokine interleukin-1 (IL-1). ARCALYST® is currently 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. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue.

ARCALYST® is in a Phase 3 clinical development program for the prevention of gout flares in patients initiating uric acid-lowering therapy. In June 2010, the Company announced positive efficacy and safety results from a Phase 3 study (PRE-SURGE 1) in gout patients initiating allopurinol therapy to lower their uric acid levels. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p<0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p<0.0001$). ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Injection site reaction, generally considered mild, was the most commonly reported adverse event with ARCALYST®.

Two other studies are ongoing in the Phase 3 program. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. The global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 and RE-SURGE are fully enrolled, and the Company expects to have initial data from both studies in the first quarter of 2011. Regeneron owns worldwide rights to ARCALYST®.

Aflibercept (VEGF Trap) – Oncology

Aflibercept, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A and PLGF, proteins that are involved in the abnormal growth of new blood vessels in solid tumors.

Aflibercept is being developed worldwide by Regeneron and its collaborator, the sanofi-aventis Group, for the potential treatment of solid tumors. Three randomized, double-blind, Phase 3 trials, all of which are fully enrolled, are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. The third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for metastatic, castration-resistant prostate cancer in combination with docetaxel/prednisone.

Final results from the VITAL and VELOUR studies are anticipated in the first half of 2011. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an Independent Data Monitoring Committee in mid-2011, with final results anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) is evaluating aflibercept as a 1st-line treatment for metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin). The AFFIRM study is fully enrolled, and initial data are anticipated in the second half of 2011.

Monoclonal Antibodies

Since 2007, Regeneron and sanofi-aventis have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. During the fourth quarter of 2009, Regeneron and sanofi-aventis expanded and extended their collaboration with the objective to advance an average of four to five antibodies into clinical development each year between 2010 and 2017. The following eight antibody candidates are currently in clinical development under the collaboration:

REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, has been evaluated in Phase 1 studies using both intravenous and subcutaneous routes of administration. REGN727 is being studied as a single agent and in combination with statin therapy. Phase 2 studies have been initiated in patients with hypercholesterolemia.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in 2011.

REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, has completed Phase 1 testing in healthy volunteers. A Phase 1b study in patients with atopic dermatitis is underway and a Phase 2 study in asthma is planned.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in oncology.

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in osteoarthritis of the knee. In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

REGN728 and *REGN846*, whose targets remain undisclosed, have entered clinical development.

Financial Results

The Company's total revenues increased to $133.7 million in the fourth quarter of 2010 from $96.8 million in the same quarter of 2009 and to $459.1 million for the full year 2010 from $379.3 million for the full year 2009. The increases were primarily due to higher collaboration revenue in 2010 in connection with the Company's antibody collaboration with sanofi-aventis. In addition, the increase in the fourth quarter of 2010 was partly due to the recognition of $20.0 million in substantive milestone payments from Bayer HealthCare.

Net product sales of ARCALYST® in the fourth quarter of 2010 were $5.3 million, compared to $5.0 million during the same period of 2009. The Company recognized $25.3 million of net product sales for the full year 2010, which included $20.5 million of ARCALYST® net product sales made during 2010 and $4.8 million of previously deferred net product sales. In 2009, the Company recognized $18.4 million of ARCALYST® net product sales.

The Company's total operating expenses increased to $146.5 million in the fourth quarter of 2010 from $136.2 million in the same quarter of 2009, and to $556.5 million for the full year 2010 from $453.4 million for the full year 2009. The increases were primarily due to higher research and development expenses arising from the Company's expanding research and development activities in 2010 and related higher employee headcount, principally in connection with the sanofi-aventis antibody collaboration. Research and development expenses for the full year 2010 rose to $489.2 million from $398.8 million in 2009.

The Company had a net loss of $14.6 million, or $0.17 per share (basic and diluted), for the fourth quarter of 2010 compared with a net loss of $36.5 million, or $0.46 per share (basic and diluted), for the fourth quarter of 2009. The Company had a net loss of $104.5 million, or $1.26 per share (basic and diluted), for the full year 2010 compared with a net loss of $67.8 million, or $0.85 per share (basic and diluted), for the full year 2009.

In October 2010, the Company completed a public offering of 6,325,000 shares of Common Stock and received net proceeds of $174.8 million. At December 31, 2010, cash and marketable securities totaled $626.9 million (including $7.5 million of restricted cash and marketable securities) compared with $390.0 million (including $1.6 million of restricted cash) at December 31, 2009.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties and actual events or results may differ materially from these forward-looking statements. These risks and uncertainties include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	December 31, 2010	December 31, 2009
ASSETS		
Cash, restricted cash, and marketable securities	626,939	$ 390,010
Receivables	93,112	65,568
Property, plant, and equipment, net	347,450	259,676
Other assets	21,931	25,948
Total assets	$ 1,089,432	$ 741,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$ 61,008	$ 52,990
Deferred revenue	340,579	182,428
Facility lease obligations	160,030	109,022
Stockholders' equity	527,815	396,762
Total liabilities and stockholders' equity	$ 1,089,432	$ 741,202

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended December 31,		For the year ended December 31,	
	2010	**2009**	**2010**	**2009**
Revenues				
Collaboration revenue	$ 117,047	$ 80,582	$ 386,725	$ 314,457
Technology licensing	10,038	10,013	40,150	40,013
Net product sales	5,269	5,000	25,254	18,364
Contract research and other	1,321	1,205	6,945	6,434
	133,675	96,800	459,074	379,268
Expenses				
Research and development	125,212	118,790	489,252	398,762
Selling, general, and administrative	20,641	17,031	65,201	52,923
Cost of goods sold	599	387	2,093	1,686
	146,452	136,208	556,546	453,371
Loss from operations	(12,777)	(39,408)	(97,472)	(74,103)
Other income (expense)				
Investment income	638	553	2,122	4,488
Interest expense	(2,458)	(1,756)	(9,118)	(2,337)
	(1,820)	(1,203)	(6,996)	2,151
Net loss before income tax benefit	(14,597)	(40,611)	(104,468)	(71,952)
Income tax benefit		(4,122)		(4,122)
Net loss	$ (14,597)	$ (36,489)	$ (104,468)	$ (67,830)
Net loss per share amounts, basic and diluted	$ (0.17)	$ (0.46)	$ (1.26)	$ (0.85)
Weighted average shares outstanding, basic and diluted	87,405	80,137	82,926	79,782

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 4/27/2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 27, 2011 (April 27, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On April 27, 2011, Regeneron Pharmaceuticals, Inc. and Bayer HealthCare issued a press release reporting positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the Phase 3 GALILEO study in patients with macular edema due to central retinal vein occlusion. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Reporting Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion, dated April 27, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: April 27, 2011

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

Number	Description
99.1	Press Release Reporting Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion, dated April 27, 2011

REGENERON

For Immediate Release

Press Release

Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion

Regulatory applications for marketing approval in the US planned in second-half of 2011 and in Europe in 2012

Tarrytown, NY, USA, and Berlin, Germany, April 27, 2011 -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Bayer HealthCare today announced positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the Phase 3 GALILEO study in patients with macular edema due to central retinal vein occlusion (CRVO). The positive results from the GALILEO study confirm the results of the similarly designed Phase 3 COPERNICUS study that were announced in December 2010.

In GALILEO, the primary endpoint at week 24 was achieved: 60.2 percent of patients receiving monthly VEGF Trap-Eye 2 milligrams (mg) gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections ($p<0.0001$). The key secondary endpoint of the study was also met: patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$).

"After reporting positive results from the VIEW 1 and VIEW 2 Phase 3 studies for the treatment of the neovascular form of age-related macular degeneration, or wet AMD, we are very pleased to now also have two positive Phase 3 trials with VEGF Trap-Eye in central retinal vein occlusion," said Kemal Malik, M.D., Head of Global Development and member of the Bayer HealthCare Executive Committee.

"With two Phase 3 trials showing impressive improvement in vision relative to control, VEGF Trap-Eye has the potential to provide patients and physicians a new treatment option for central retinal vein occlusion," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories.

As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. The incidence of ocular serious adverse events was higher in the sham group compared to the active treatment arm (8.8% vs 2.9%).

Regeneron intends to submit a regulatory application for marketing approval in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in Europe in 2012.

Detailed results of the GALILEO study will be presented at the EURETINA Congress in London in May, 2011.

About the Phase 3 CRVO Program
Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the almost identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies received six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections.

Patients in both trials were randomized in a 3:2 ratio with 114 patients randomized to receive VEGF Trap-Eye and 73 randomized to the control arm in COPERNICUS and 104 patients randomized to receive VEGF Trap-Eye and 68 randomized to the control arm in GALILEO. At the end of the initial six months, all patients randomized to VEGF Trap-Eye are dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months were eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients are eligible for rescue laser treatment. Visual acuity is measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

Phase 3 GALILEO Study Results
In the GALILEO study, 60.2 percent of patients receiving VEGF Trap-Eye 2mg monthly gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections ($p<0.0001$), the primary endpoint of the study. Patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

VEGF Trap-Eye was generally well tolerated and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were 2.9 percent and were more frequent in the control group (8.8 percent). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

About Central Retinal Vein Occlusion (CRVO)
Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

About VEGF Trap-Eye
VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Bayer HealthCare and Regeneron are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders.

Regeneron submitted a Biologics License Application (BLA) for marketing approval in wet AMD in the U.S. in February 2011 and received a Priority Review designation. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer plans to file regulatory submissions in Europe in the second quarter of 2011.

In April 2011, Bayer HealthCare and Regeneron announced the initiation of a Phase 3 program in DME.

Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally the profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 16.913 billion (2010), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55.700 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Regeneron Forward-Looking Statements

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

Bayer Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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Electronic Patent Application Fee Transmittal

Application Number:	16397267
Filing Date:	29-Apr-2019
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Filer:	Karl Bozicevic/Kimberly Zuehlke
Attorney Docket Number:	REGN-008CIPCON5

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**240**

Electronic Acknowledgement Receipt

EFS ID:	40026253
Application Number:	16397267
International Application Number:	
Confirmation Number:	8135
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Customer Number:	96387
Filer:	Karl Bozicevic/Kimberly Zuehlke
Filer Authorized By:	Karl Bozicevic
Attorney Docket Number:	REGN-008CIPCON5
Receipt Date:	16-JUL-2020
Filing Date:	29-APR-2019
Time Stamp:	18:13:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$240
RAM confirmation Number	E20207FI14310791
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	0725US06_2020-07-16_Supp_IDS_trans_REGN-008CIPCON5.pdf	51813 ce7a69af2beb32febc3c34838873e77d310fecea	no	2
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	0725US06__2020-07-16_Supp_IDS_SB08A_REGN-008CIPCON5.pdf	63978 3dd2daa46283e643f9bbd4d1897fab36d2e00824	no	5
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Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO2005000895A2.pdf	2338182 6363e90be1b6d4d24923286378ef404ecffe18c3	no	38
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Information:					
4	Foreign Reference	WO2004106378A2.pdf	1507654 b6c832b47fd56959cb880da99e6703a41bf742cc	no	23
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Information:					
5	Non Patent Literature	01_Benz_May_2007.pdf	46129 dff86fc070ae43858a162bc440b012b07665a2f9	no	2
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6	Non Patent Literature	02_Do_May_2007.pdf	53639 d211e1d8d8063e474ab9ec77238ff8a5a33fbdb06	no	2
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7	Non Patent Literature	03_Do_April_2009.pdf	47066 fd7e6416950ad2213097da0329a57a620e0666ce	no	2
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15	Non Patent Literature	11_NCT00320788_2012.pdf	292436 caf8ed62780436c916ce5349682ef9800be64ba5	no	31
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16	Non Patent Literature	12_NCT00320814_2006-2011.pdf	565177 23acdc433c5f955442dacee7bac57e5c638654ca	no	30
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38	Non Patent Literature	34_20090430_REGENERON_PHARMACEUTICALS_INC_10-Q_4_30.pdf	1262748 64632b48b21ea7789c60d93cd35101c4149910c9	no	87
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54	Non Patent Literature	50_20081104_REGENERON_PHARMACEUTICALS_INC_8-K_11_4.pdf	253271 77e93d891ebeacae9e58a2cacabbb2fd6cb2d355	no	15
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61	Fee Worksheet (SB06)	fee-info.pdf	31040 7194a5040ee29918416460a2052ce622c08696e9	no	2
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Information:					
		Total Files Size (in bytes):	77134681		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronically Filed

INFORMATION DISCLOSURE STATEMENT	Attorney Docket No.	REGN-008CIPCON5
	Confirmation No.	8135
	First Named Inventor	George D. Yancopoulos
	Application Number	16/397,267
	Filing Date	April 29, 2019
	Group Art Unit	1647
Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Examiner Name	Jon McClelland Lockard
	Title: "*Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders*"	

Sir:

Applicant submits herewith documents which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56. This submission is not intended to constitute an admission that any document referred to therein is "prior art" for this invention unless specifically designated as such. A listing of the documents is shown on enclosed Form PTO/SB/08A and copies of the foreign patents and non-patent literature are also enclosed.

The publications discussed herein are provided to comply with the duty to disclose in accordance with 37 C.F.R. § 1.56. However, nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed

The Examiner is requested to make the documents listed on the enclosed PTO/SB/08A of record in this application. Applicant would appreciate the Examiner initialing and returning the initialed copy of form PTO/SB/08A, indicating the documents cited therein have been considered and made of record herein.

Statements

☒ **No statement**

☐ **PTA Statement under 37 CFR § 1.704(d)(1):** Each item of information contained in the information disclosure statement filed herewith:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by

any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

☐ **IDS Statement under 37 CFR § 1.97(e)(1):** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ **IDS Statement under 37 CFR § 1.97(e)(2):** No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Fees

☐ No fee is believed to be due.

☒ The appropriate fee set forth in 37 C.F.R. §1.17(p) accompanies this information disclosure statement.

The Commissioner is hereby authorized to charge any underpayment of fees up to a strict limit of $3,000.00 beyond that authorized on the credit card, but not more than $3,000.00 in additional fees due with any communication for the above referenced patent application, including but not limited to any necessary fees for extensions of time, or credit any overpayment of any amount to Deposit Account No. 50-0815, order number REGN-008CIPCON5.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 16 July 2020

By: /Karl Bozicevic, Reg. No. 28,807/
Karl Bozicevic
Reg. No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP
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Telephone: (650) 327-3400
Facsimile: (650) 327-3231

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 5/3/2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 3, 2011 (May 3, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On May 3, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2011. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated May 3, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: May 3, 2011

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

Number	Description
99.1	Press Release dated May 3, 2011.

REGENERON

For Immediate Release

Press Release

Regeneron Reports First Quarter 2011 Financial and Operating Results

Tarrytown, New York (May 3, 2011) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial results for the first quarter of 2011 and provided an update on development programs and upcoming milestones.

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) – Ophthalmologic Diseases

VEGF Trap-Eye is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC has rights to market VEGF Trap-Eye outside the U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

In February 2011, Regeneron submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for VEGF Trap-Eye for the treatment of the neovascular form of age-related macular degeneration (wet AMD). In April 2011, the FDA accepted the BLA for filing and granted the Company's request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011.

Also in February 2011, data from the Phase 3 VIEW 1 and VIEW 2 trials of VEGF Trap-Eye in patients with wet AMD and the Phase 3 COPERNICUS trial in macular edema due to central retinal vein occlusion (CRVO) were presented at the Bascom Palmer Eye Institute's Angiogenesis, Exudation and Degeneration 2011 meeting. Results of the Phase 2 DA VINCI trial of VEGF Trap-Eye in diabetic macular edema (DME) were also presented.

In April 2011, Regeneron and Bayer HealthCare announced positive top-line results for VEGF Trap-Eye in the Phase 3 GALILEO study in patients with macular edema due to CRVO. The positive results from the GALILEO study confirmed the results of the similarly designed COPERNICUS study that were announced in December 2010. In GALILEO, the primary endpoint at week 24 was achieved: 60.2% of patients receiving 2 milligrams (mg) of VEGF Trap-Eye monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections ($p<0.0001$). The key secondary endpoint of the study was also met: patients receiving 2 mg of VEGF Trap-Eye monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$). As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. Detailed results of the GALILEO study will be presented at the EURETINA Congress in London in May 2011.

Based on these positive results, Regeneron intends to submit a regulatory application for marketing approval for VEGF Trap-Eye in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in Europe in 2012.

In April 2011, Regeneron and Bayer Healthcare announced that Bayer HealthCare has initiated the Phase 3 VIVID-DME study of VEGF Trap-Eye in DME in Australia. The trial will also be conducted in Europe and Japan. Regeneron intends to commence a second Phase 3 study (VISTA-DME) in DME later in 2011 in the U.S., Canada, and other countries.

ZALTRAP™ (aflibercept) – Oncology

ZALTRAP™, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A, VEGF-B, and PlGF, proteins that are involved in the abnormal growth of new blood vessels in solid tumors. ZALTRAP™ is being developed worldwide by Regeneron and its collaborator, the sanofi-aventis Group, for the potential treatment of solid tumors.

In April 2011, Regeneron and sanofi-aventis announced that the Phase 3 VELOUR trial evaluating ZALTRAP™ in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in the second-line treatment of metastatic colorectal cancer (mCRC). Full results will be presented at an upcoming medical meeting. The most frequent adverse events reported with ZALTRAP™ in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection, hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Based upon these positive findings, Regeneron and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the European Medicines Agency in the second half of 2011.

In February 2011, Regeneron and sanofi-aventis announced results from the Phase 3 VITAL trial evaluating ZALTRAP™ for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding ZALTRAP™ to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of ZALTRAP™ to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the ZALTRAP™ arm compared to 8.9% in the placebo arm. The types and frequencies of adverse events reported in the ZALTRAP™ treatment arm were generally consistent with those reported in previous studies with anti-VEGF agents. The most frequent Grade 3/4 adverse events included fatigue, stomatitis, disease progression, and hypertension.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAP™ as a first-line treatment for metastatic, castration-resistant prostate cancer in combination with docetaxel/prednisone. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an Independent Data Monitoring Committee in mid-2011, and final results are anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) is evaluating ZALTRAP™ as a first-line treatment for metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin). The AFFIRM study is fully enrolled, and initial data are anticipated in the second half of 2011.

ARCALYST® (rilonacept) – Gout

ARCALYST® is a fusion protein that blocks the cytokine interleukin-1 (IL-1). ARCALYST® is currently available for prescription in the U.S. 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. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue.

In February 2011, Regeneron reported the results of its second and third Phase 3 studies of ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy and announced that, based on these studies and a previously reported Phase 3 study, the Company plans to submit a supplemental BLA for U.S. regulatory approval of ARCALYST® in this setting in mid-2011. The Company reported that in the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group ($p<0.0001$). These results were consistent with those in the identical Phase 3 efficacy study (PRE-SURGE 1) reported in June 2010. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most frequently reported adverse event was upper respiratory tract infection (15.5% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 12.2% with placebo).

Regeneron also announced that in the third Phase 3 study (RE-SURGE), which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. RE-SURGE evaluated 1,315 patients who were at risk for gout flares while initiating or taking uric acid-lowering drug treatment. Other than injection site reactions, the incidence of treatment-emergent adverse events was generally well-balanced among the 985 patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg and the 330 patients who received placebo. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST® (15.2%) than with placebo (3.3%). Overall, the cumulative rate of infections was 20.1% in patients treated with ARCALYST® and 19.1% in placebo patients. Serious infections were reported in 0.5% of patients treated with ARCALYST® and 0.9% of placebo patients. Deaths were reported for 0.3% of patients treated with ARCALYST® and 0.9% of placebo patients.

In the RE-SURGE study, ARCALYST® also met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period ($p<0.0001$). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Regeneron owns worldwide rights to ARCALYST®.

Monoclonal Antibodies

Since 2007, Regeneron and sanofi-aventis have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. During the fourth quarter of 2009, Regeneron and sanofi-aventis expanded and extended their collaboration with the objective to advance an average of four to five antibodies into clinical development each year between 2010 and 2017. The following eight antibody candidates are currently in clinical development under the collaboration:

REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, has been evaluated in Phase 1 studies using both intravenous and subcutaneous routes of administration. REGN727 is being studied as a single agent and in combination with statin therapy. Phase 2 studies have been initiated in combination with statins in patients with hypercholesterolemia.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in mid-2011.

REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, has completed Phase 1 testing in healthy volunteers. A Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma are underway.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in an oncology setting.

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in osteoarthritis of the knee. In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

REGN728 and *REGN846*, whose targets remain undisclosed, have entered clinical development.

Financial Results

The Company's total revenues increased to $112.2 million in the first quarter of 2011 from $103.5 million in the same quarter of 2010. The increases were primarily due to higher collaboration revenue in the first quarter of 2011 in connection with the Company's antibody collaboration with sanofi-aventis.

Net product sales of ARCALYST® in the first quarter of 2011 were $4.4 million. Net product sales of ARCALYST® in the first quarter of 2010 were $9.9 million, which included $5.1 million of net product sales made during the quarter and $4.8 million of previously deferred net product sales.

The Company's total operating expenses increased to $153.2 million in the first quarter of 2011 from $132.4 million in the same quarter of 2010. The increases were primarily due to higher research and development expenses arising from the Company's expanding research and development activities in 2011 and related higher employee headcount, principally in connection with the sanofi-aventis antibody collaboration. Research and development expenses in the first quarter of 2011 rose to $129.4 million from $117.5 million in the same quarter of 2010.

The Company had a net loss of $43.4 million, or $0.49 per share (basic and diluted), for the first quarter of 2011 compared with a net loss of $30.5 million, or $0.38 per share (basic and diluted), for the first quarter of 2010.

At March 31, 2011, cash and marketable securities totaled $607.6 million (including $7.5 million of restricted cash and marketable securities) compared with $626.9 million (including $7.5 million of restricted cash and marketable securities) at December 31, 2010.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended March 31, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	March 31, 2011	December 31, 2010
ASSETS		
Cash, restricted cash, and marketable securities	$ 607,582	$ 626,939
Receivables	88,156	93,112
Property, plant, and equipment, net	357,423	347,450
Other assets	21,132	21,931
Total assets	$ 1,074,293	$ 1,089,432
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$ 65,782	$ 61,008
Deferred revenue	330,269	340,579
Facility lease obligations	160,151	160,030
Stockholders' equity	518,091	527,815
Total liabilities and stockholders' equity	$ 1,074,293	$ 1,089,432

REGENERON PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS (Unaudited)
(In thousands, except per share data)

	For the three months ended March 31,	
	2011	**2010**
Revenues		
Collaboration revenue	$ 97,810	$ 81,758
Technology licensing	7,845	10,038
Net product sales	4,427	9,852
Contract research and other	2,122	1,886
	112,204	103,534
Expenses		
Research and development	129,392	117,471
Selling, general, and administrative	23,411	14,223
Cost of goods sold	382	717
	153,185	132,411
Loss from operations	(40,981)	(28,877)
Other income (expense)		
Investment income	1,037	439
Interest expense	(3,719)	(2,084)
	(2,682)	(1,645)
Net loss before income tax benefit	(43,663)	(30,522)
Income tax benefit	(216)	
Net loss	$ (43,447)	$ (30,522)
Net loss per share amounts, basic and diluted	$ (0.49)	$ (0.38)
Weighted average shares outstanding, basic and diluted	89,162	81,169

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 6/21/2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 20, 2011 (June 17, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On June 17, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing that the Dermatologic and Ophthalmic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted unanimously to recommend that the FDA approve EYLEA™ (aflibercept ophthalmic solution), also known as VEGF Trap-Eye, for the treatment of the neovascular form of age-related macular degeneration (wet AMD) at a dose of 2 milligrams (mg) every eight weeks, following three initial doses given every four weeks.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated June 17, 2011, Announcing that EYLEA™ (aflibercept ophthalmic solution) Received Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee.

SIGNATURES

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 hereunto duly authorized.

Date: June 20, 2011

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

Number	Description
99.1	Press Release, dated June 17, 2011, Announcing that EYLEA™ (aflibercept ophthalmic solution) Received Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee

REGENERON

For Immediate Release

Press Release

Regeneron Announces EYLEA™ (aflibercept ophthalmic solution) Receives Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee

Tarrytown, NY (June 17, 2011) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that the Dermatologic and Ophthalmic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has voted unanimously to recommend that the FDA approve EYLEA™, also known as VEGF Trap-Eye, for the treatment of the neovascular form of age-related macular degeneration (wet AMD) at a dose of 2 milligrams (mg) every eight weeks, following three initial doses given every four weeks.

The committee's recommendation will be considered by the FDA in its review of the Biologics License Application (BLA) for EYLEA, but the committee's recommendation is not binding on the FDA. Regeneron submitted a BLA for marketing approval in wet AMD in the U.S. in February 2011 and received a Priority Review designation. Under Priority Review, the target date for an FDA decision on the EYLEA BLA is August 20, 2011.

"The positive recommendation by the advisory committee is an important step toward providing wet AMD patients with a new treatment option that could potentially reduce the burden that exists with current therapies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "We look forward to continuing to work with the FDA as it completes its evaluation of the EYLEA BLA."

About EYLEA
Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as age-related macular degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit vascular permeability and lead to edema.

EYLEA (aflibercept ophthalmic solution), also known as VEGF Trap-Eye, is a fully human fusion protein, consisting of portions of VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). EYLEA is a specific and highly potent blocker of these growth factors. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Regeneron and Bayer HealthCare are collaborating on the global development of EYLEA for the treatment of the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders. Bayer submitted an application for marketing authorization in Europe in wet AMD in June 2011.

The EYLEA wet AMD regulatory submissions are based on the positive results from two Phase 3 trials, the VIEW 1 study and the VIEW 2 study. In these trials, all regimens of EYLEA, including 2 milligrams (mg) of EYLEA dosed every two months (following three loading doses), successfully met the primary endpoint of non-inferiority compared to the current standard of care, ranibizumab 0.5 mg dosed every month. The primary endpoint analysis was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. A generally favorable safety profile was observed for both EYLEA and ranibizumab. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters.

Bayer HealthCare will market EYLEA™ outside the United States, where the companies will share equally the profits from any future sales of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

Regeneron Forward Looking Statement
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended March 31, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 8/22/2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 22, 2011 (August 22, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On August 22, 2011, at the American Society of Retina Specialists meeting in Boston, Massachusetts, data from the Phase 3 COPERNICUS Study of the safety, efficacy, and tolerability of repeated intravitreal administration of VEGF Trap-Eye in patients with macular edema secondary to central retinal vein occlusion will be presented by W. Lloyd Clark, M.D. A copy of the slides that will be presented is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study

SIGNATURES

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 hereunto duly authorized.

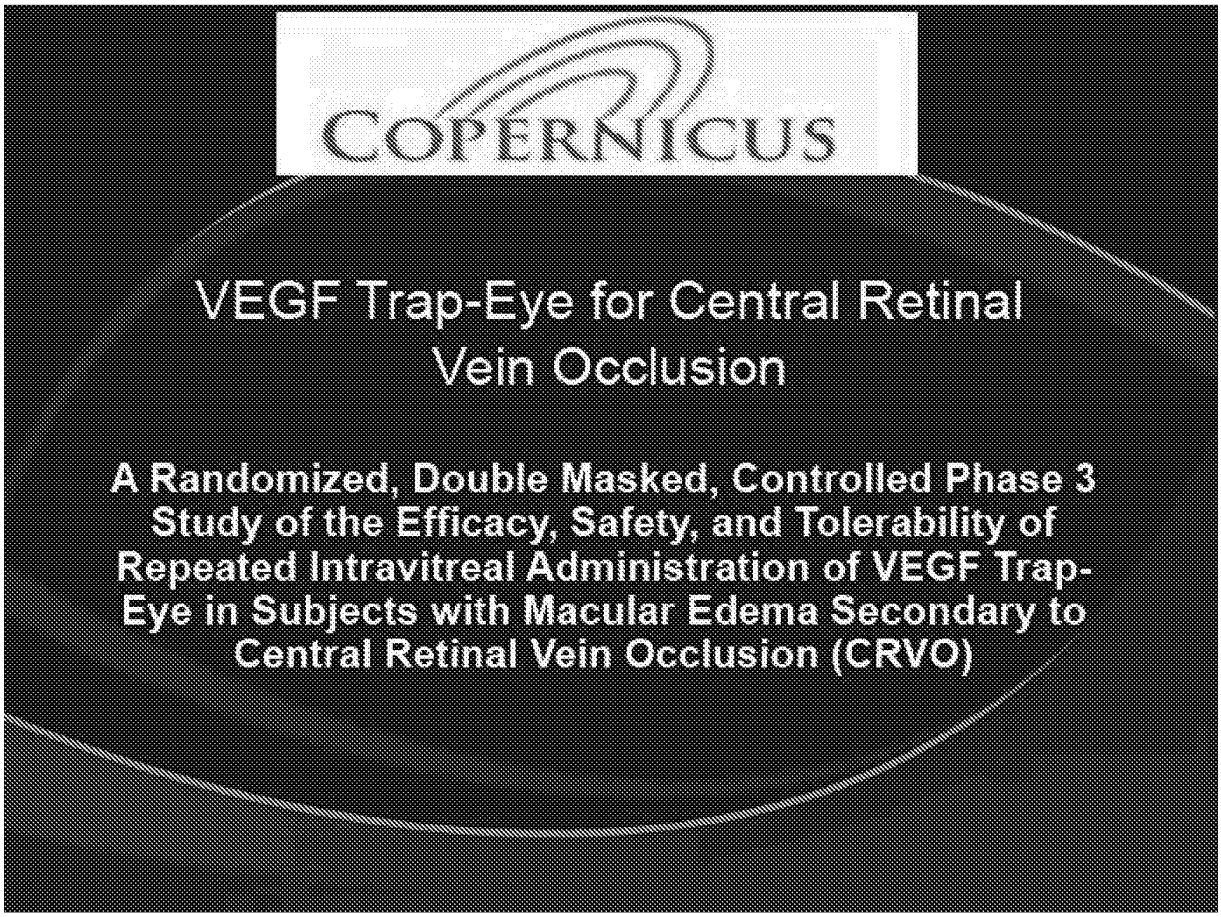
Date: August 22, 2011

REGENERON PHARMACEUTICALS, INC.

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

Exhibit Index

Number	Description
99.1	Presentation entitled VEGF Trap-Eye in CRVO: 1-year Results of the Phase 3 COPERNICUS Study


COPERNICUS
VEGF Trap-Eye for Central Retinal Vein Occlusion
A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects with Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO)

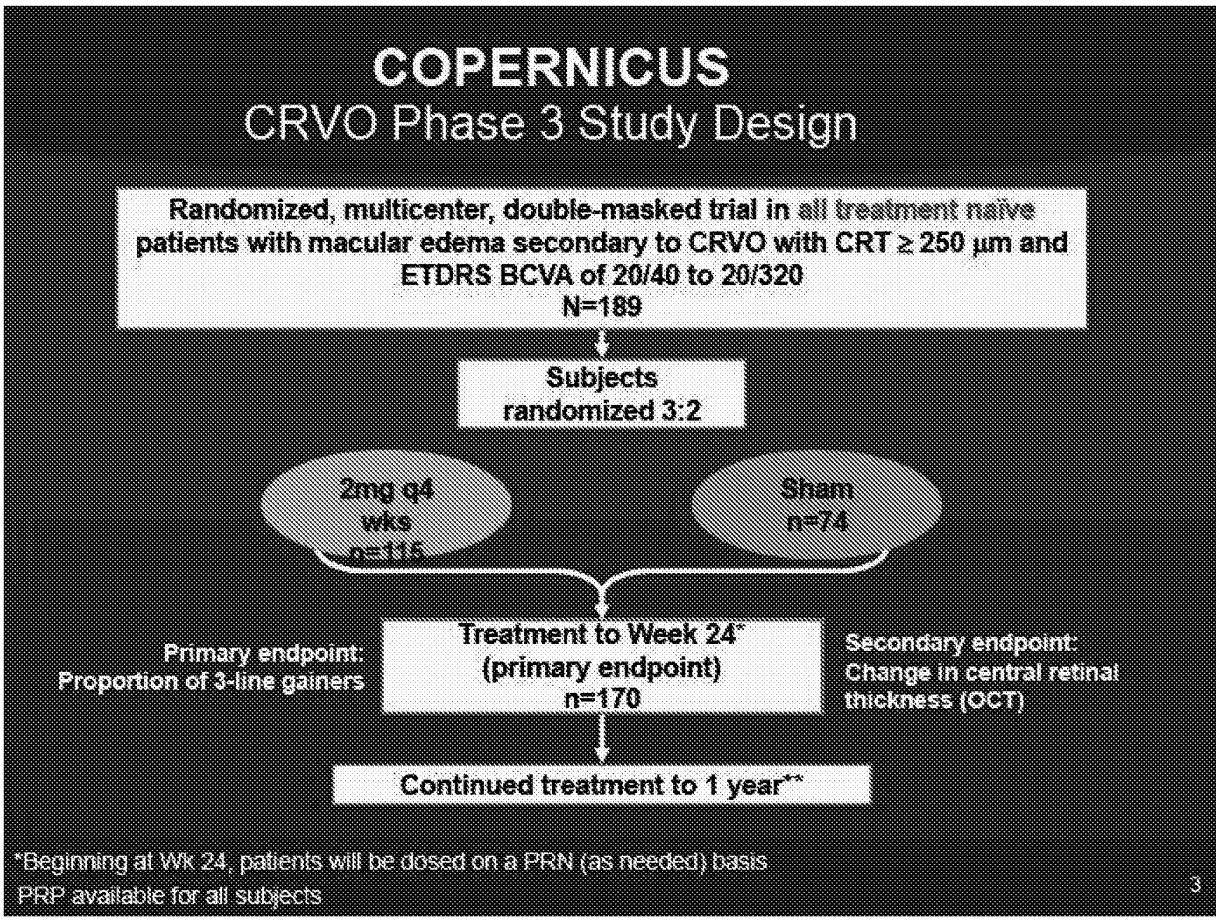
Introduction

- CRVO is an obstruction of the retinal venous system due to thrombus formation
- Prevalence currently of all RVO 0.7–1.6% and increases with age
  - BRVO 3 to 4 times greater incidence versus CRVO

Nonischemic
Up to 50% have visual acuity decrease to ≤ 20/200
< 10% recover normal visual acuity[1,2]
34% progress to ischemic by 3 years; 15% convert in first 4 months[2]
Ischemic
Up to > 90% have final visual acuity 20/200 or worse[1]
37% progress to rubeosis by 4 months[2]

1. Morley et al. Chapter 6.17. In: Ophthalmology. 2003.
2. Dennistion et al. Oxford Handbook of Ophthalmology. 2006.

Samsung Bioepis Exhibit 1012 - Page 5137
Biocon Exhibit 1012 - Page 5137


COPERNICUS
CRVO Phase 3 Study Design
Randomized, multicenter, double-masked trial in all treatment naive patients with macular edema secondary to CRVO with CRT ≥ 250 μm and ETDRS BCVA of 20/40 to 20/320
N=189
Subjects randomized 3:2
2mg q4 wks n=115
Sham n=74
Primary endpoint: Proportion of 3-line gainers
Treatment to Week 24* (primary endpoint) n=170
Secondary endpoint: Change in central retinal thickness (OCT)
Continued treatment to 1 year**
*Beginning at Wk 24, patients will be dosed on a PRN (as needed) basis
PRP available for all subjects
3

COPERNICUS
Key Exclusion Criteria

- Treatment naïve patients
- Previous use of intraocular or periocular corticosteroids in the study eye
- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months

4

COPERNICUS
Patient Disposition

	Sham	VTE 2q4
Randomized	74	115
Received Study Medication	74 (100%)	114 (99.1%)*
Completed Week 24	60 (81.1%)	110 (95.7%)
Discontinuation Before Wk 24	14 (18.9%)	5 (4.3%)
Withdrawal Of Consent[%]	1 (1.4%)	3 (2.6%)
Protocol Deviation[&]	1 (1.4%)	0
Adverse Event[#]	3 (4.1%)	0
Death[^]	2 (2.7%)	0
Lost To Follow-Up	2 (2.7%)	1 (0.9%)
Treatment Failure	4 (5.4%)	0
Other[†]	1 (1.4%)	1 (0.9%)

*One patient was randomize but not treated after a retinal tear was identified at Visit 2.
% Sham: VA Reduced 2q4: Lung cancer, unknown x2
& Sham: Bilateral CRVO
Sham: Neovascular glaucoma, retinal tear, vitreous hemorrhage/NVG
^ Sham: MI and arrhythmia
† Sham: Lack of efficacy 2q4: patient never treated

Samsung Bioepis Exhibit 1012 - Page 5140
Biocon Exhibit 1012 - Page 5140

COPERNICUS
Baseline Demographics

	Sham	VTE 2q4
n (full analysis set)	73	114
Age: years (SD)	67.5 (14.29)	65.5 (13.57)
Gender		
Women (%)	35 (48%)	45 (39%)
Men (%)	38 (52%)	69 (61%)
Race (%)		
White	59 (80.8%)	88 (77.2%)
Black	5 (6.8%)	5 (4.4%)
Asian	2 (2.7%)	7 (6.1%)
American Indian/Alaska Native	0	2 (1.8%)
Native Hawaiian/Pacific Islander	1 (1.4%)	0
Not Reported/Multi racial	6 (8.2%)	12 (10.5%)

6

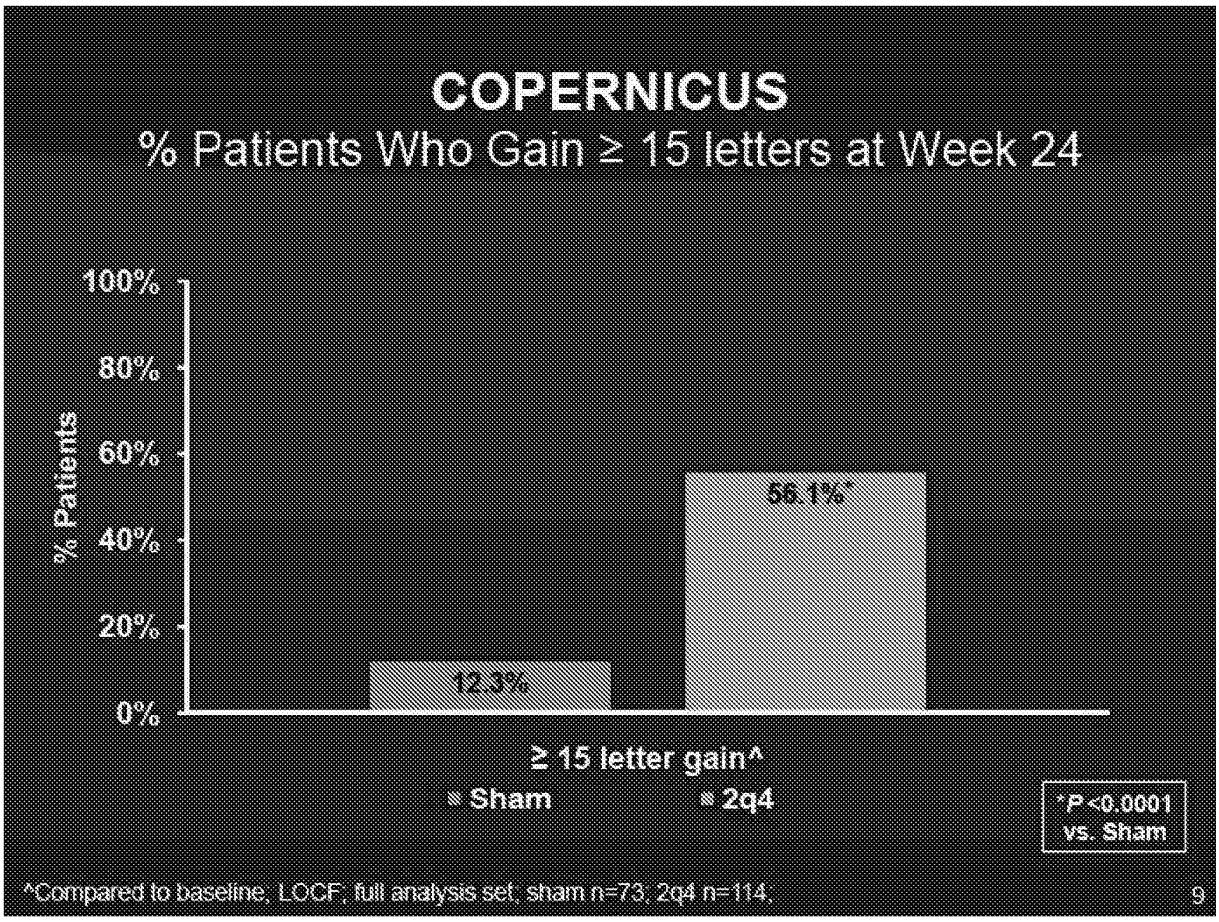
COPERNICUS
Baseline Disease Characteristics

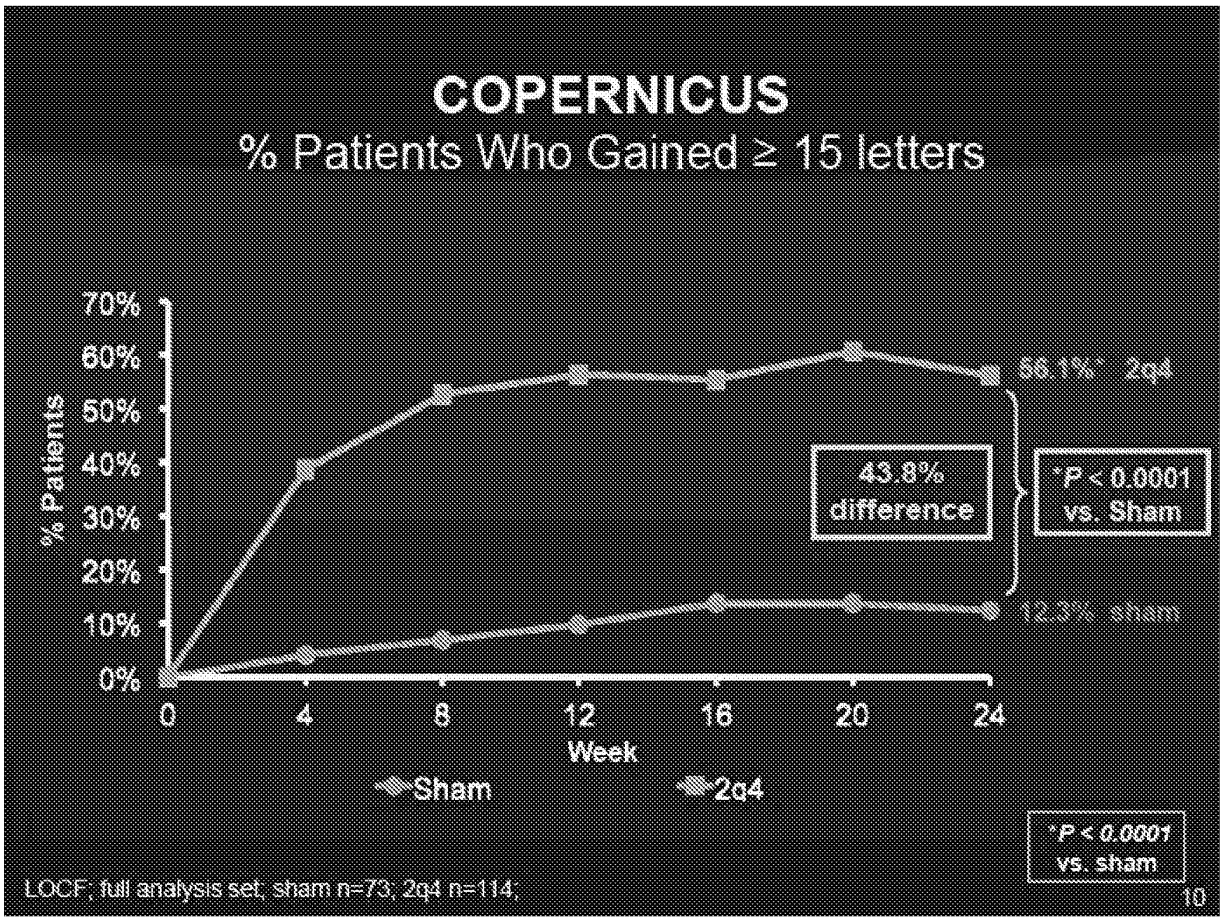
	Sham	VTE 2q4
n (full analysis set)	73	114
ETDRS BCVA letter score (SD) Snellen Equivalent	48.9 (14.4) 20/126	50.7 (13.9) 20/100
BCVA > 20/200 (%)	55 (75.3)	86 (75.4)
BCVA ≤ 20/200 (%)	18 (24.7)	28 (24.6)
Central Retinal Thickness µm (SD)	672.4 (245.3)	661.7 (237.4)
Baseline perfusion status n (%)		
Perfused*	50 (68.5%)	80 (70.2%)
Non-perfused	12 (16.4%)	14 (12.3%)
Indeterminate	10 (13.7%)	18 (15.8%)
Missing	1 (1.4%)	2 (1.8%)

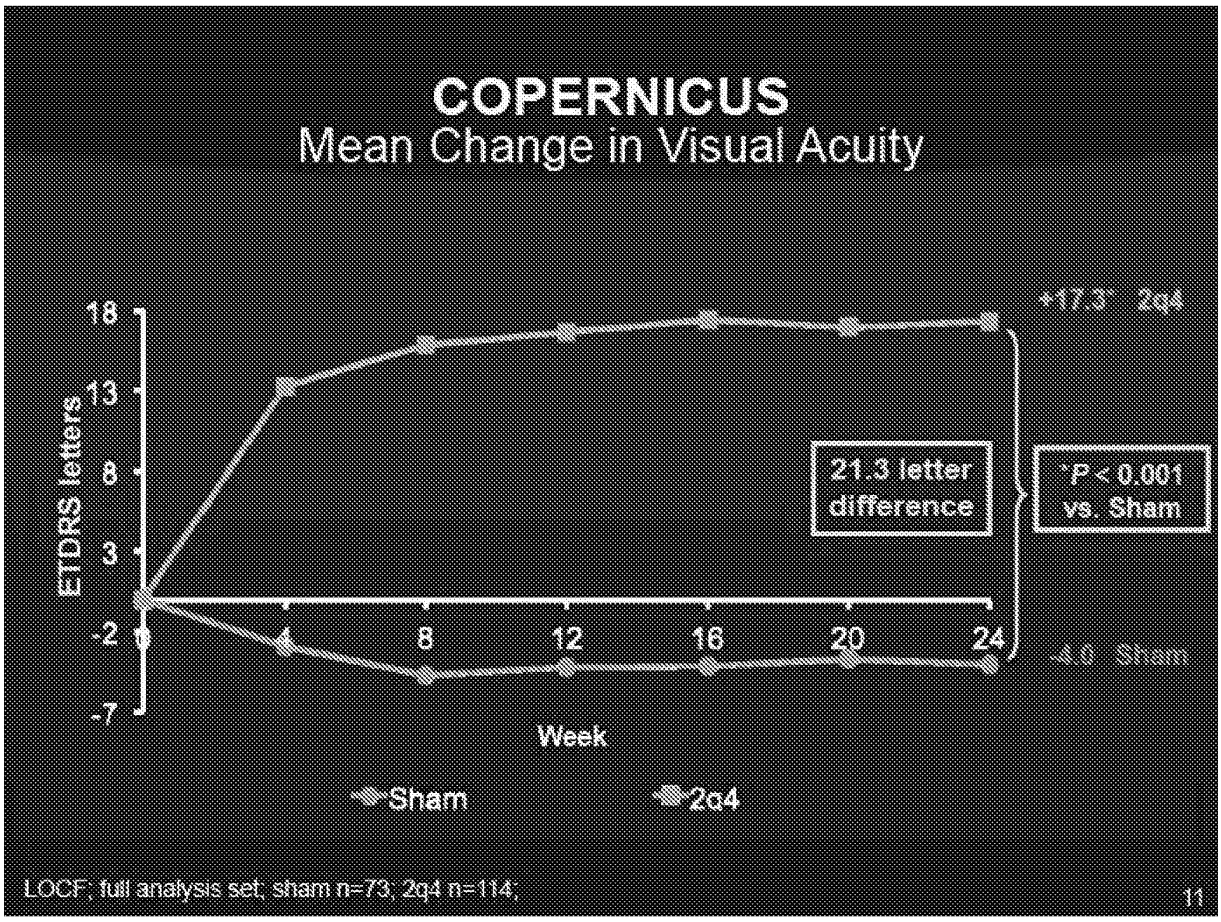
*Less than 10 DA of non perfusion

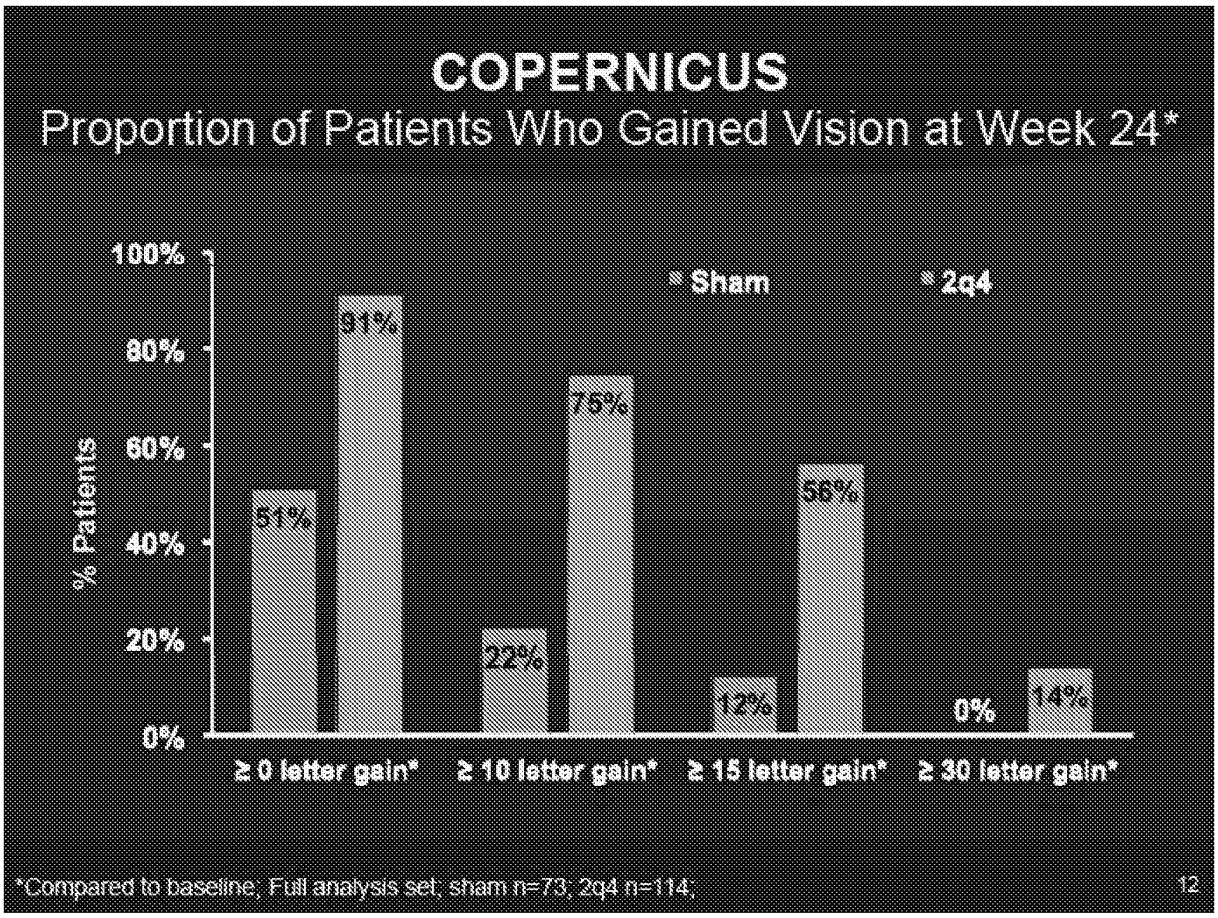
Samsung Bioepis Exhibit 1012 - Page 5142
Biocon Exhibit 1012 - Page 5142

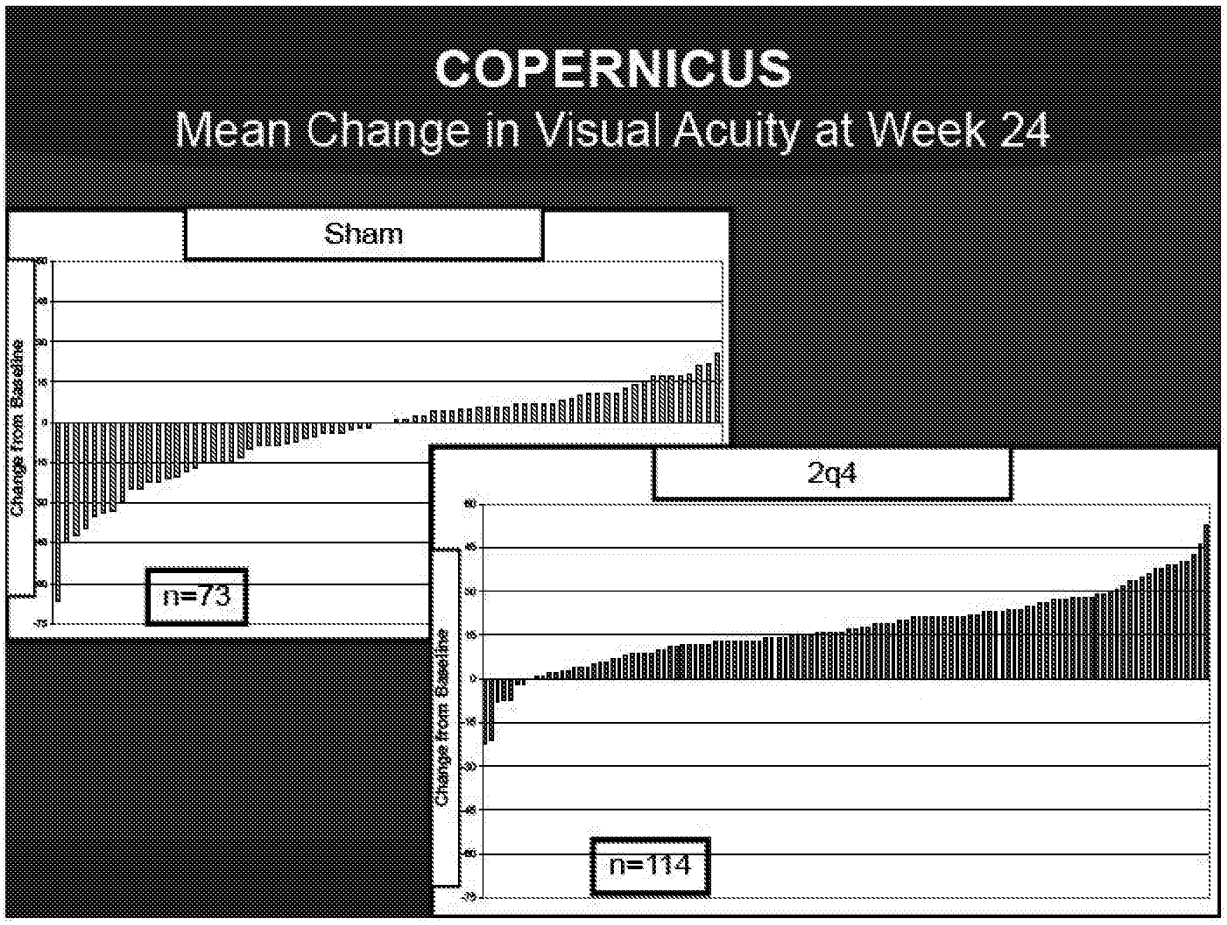

EFFICACY

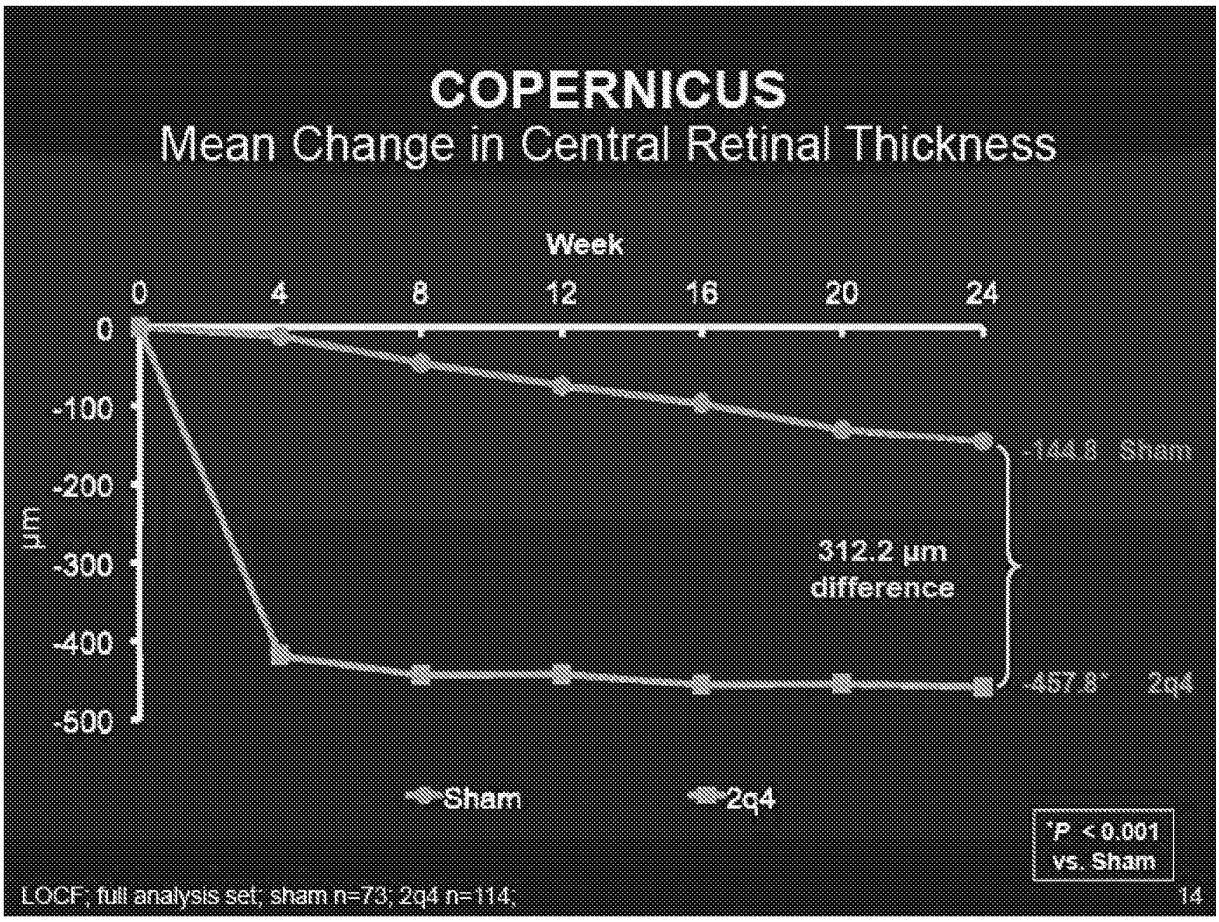

COPERNICUS
% Patients Who Gain ≥ 15 letters at Week 24
100%
80%
60%
40%
20%
0%
% Patients
12.3%
56.1%*
≥ 15 letter gain^
Sham
2q4
*P <0.0001 vs. Sham
^Compared to baseline, LOCF; full analysis set; sham n=73; 2q4 n=114.
9

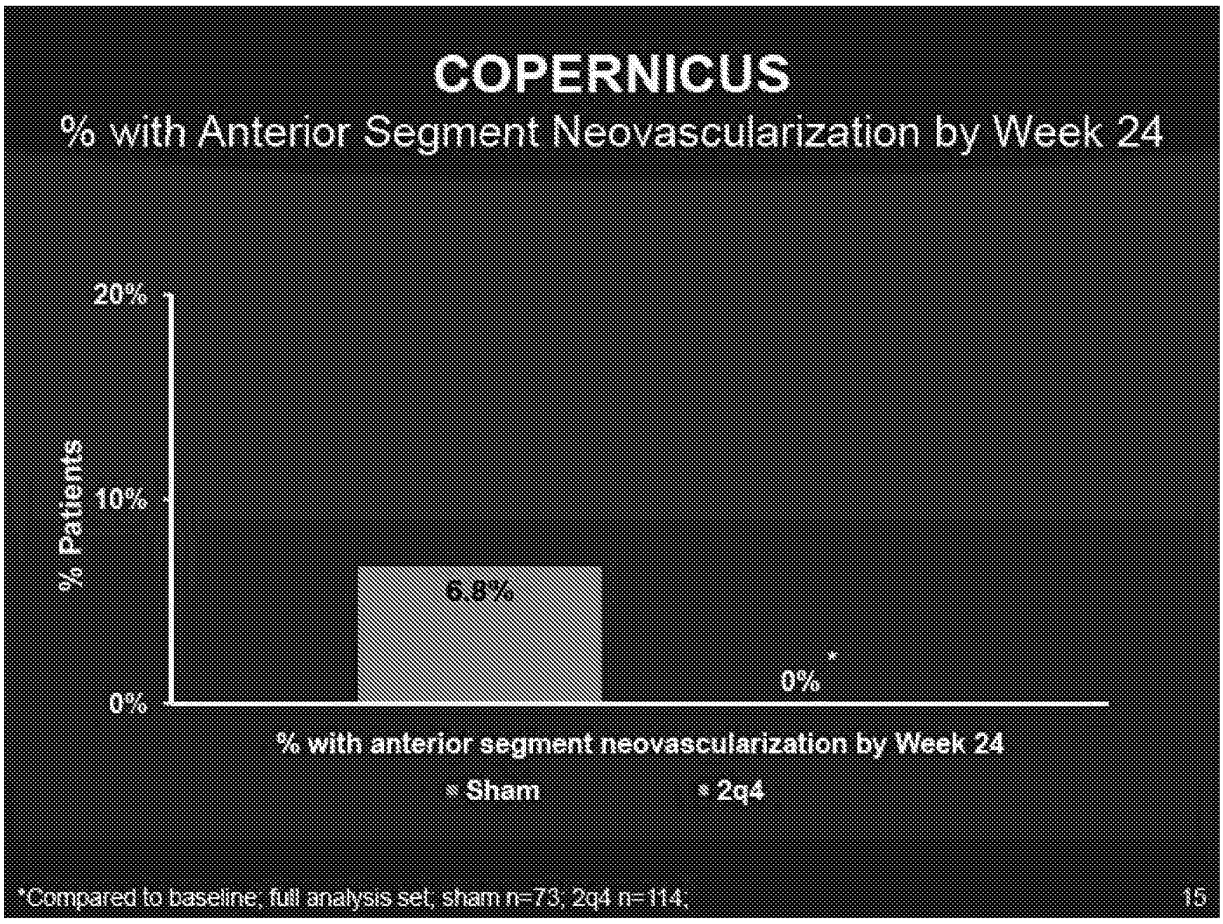

COPERNICUS
% Patients Who Gained ≥ 15 letters
% Patients
70%
60%
50%
40%
30%
20%
10%
0%
0
4
8
12
16
20
24
Week
Sham
2q4
56.1%* 2q4
43.8% difference
*P < 0.0001 vs. Sham
12.3% sham
*P < 0.0001 vs. sham
LOCF; full analysis set; sham n=73; 2q4 n=114;
10

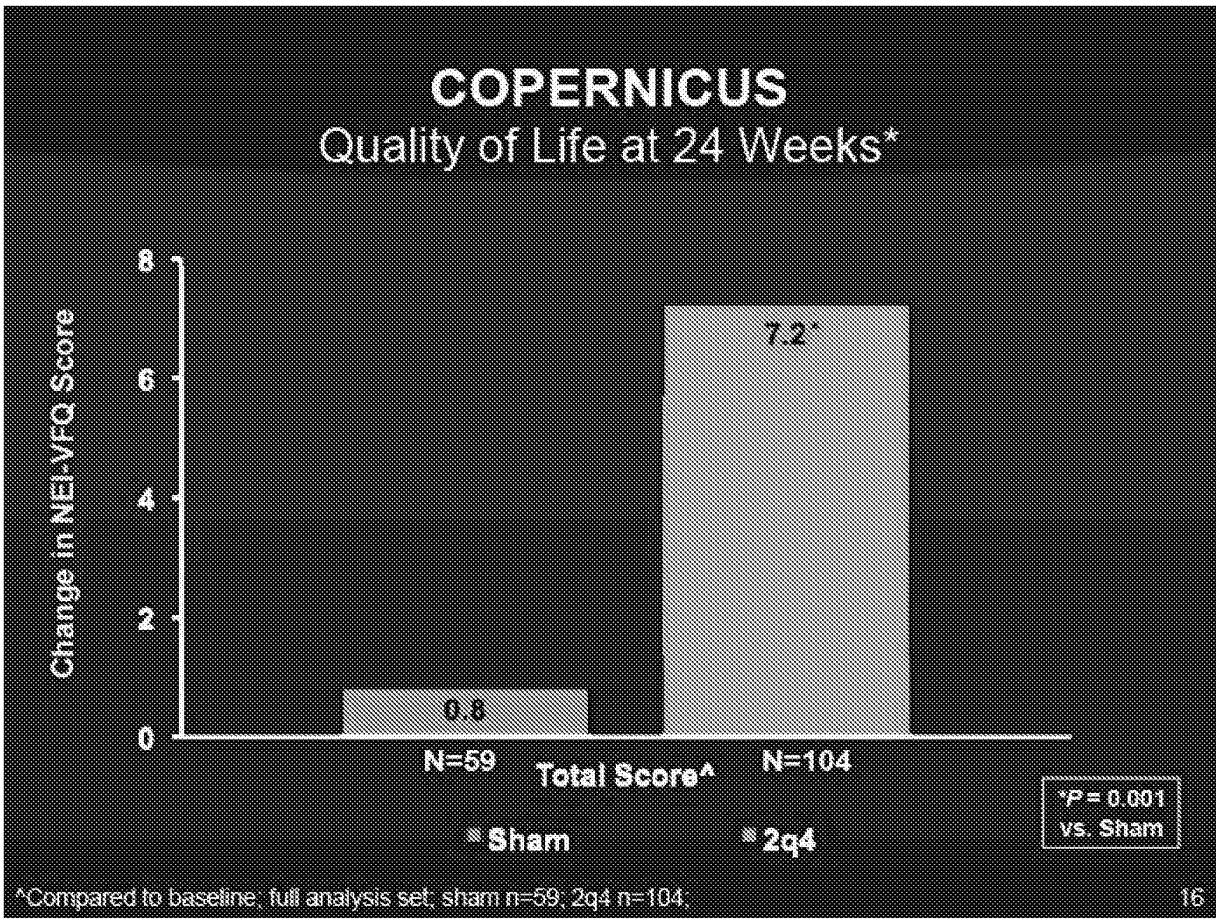

COPERNICUS
Mean Change in Visual Acuity
ETDRS letters
18
13
8
3
-2
-7
0
4
8
12
16
20
24
Week
+17.3* 2q4
-4.0 Sham
21.3 letter difference
*P < 0.001 vs. Sham
Sham
2q4
LOCF; full analysis set; sham n=73, 2q4 n=114;
11

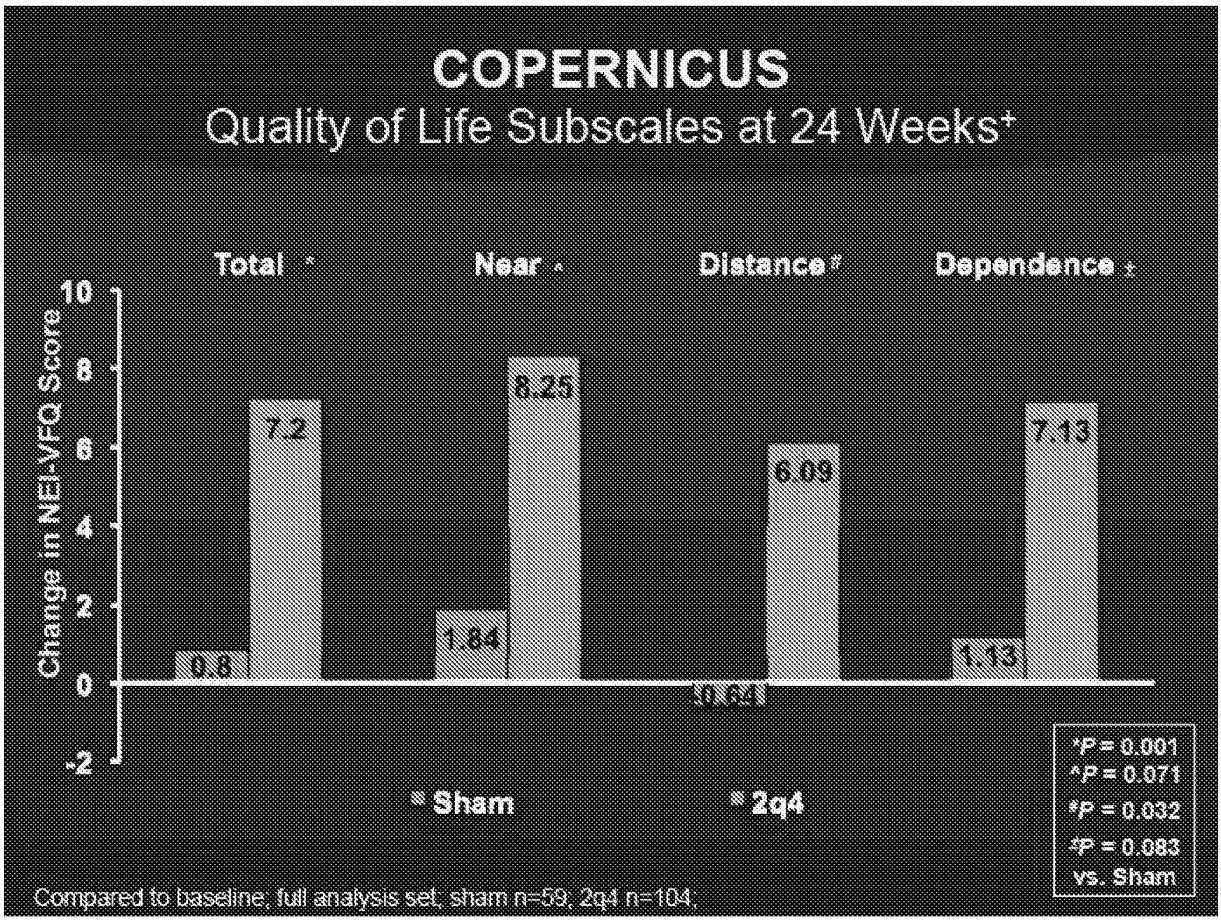

COPERNICUS
Proportion of Patients Who Gained Vision at Week 24*
100%
80%
60%
40%
20%
0%
% Patients
Sham
2q4
51%
91%
22%
75%
12%
56%
0%
14%
≥ 0 letter gain*
≥ 10 letter gain*
≥ 15 letter gain*
≥ 30 letter gain*
*Compared to baseline; Full analysis set; sham n=73; 2q4 n=114;
12


COPERNICUS
Mean Change in Visual Acuity at Week 24
Sham
Change from Baseline
n=73
2q4
Change from Baseline
n=114


COPERNICUS
Mean Change in Central Retinal Thickness
Week
0
4
8
12
16
20
24
0
-100
-200
-300
-400
-500
µm
-144.6 Sham
312.2 µm
difference
-457.8* 2q4
Sham
2q4
*P < 0.001
vs. Sham
LOCF; full analysis set; sham n=73; 2q4 n=114;
14


COPERNICUS
% with Anterior Segment Neovascularization by Week 24
20%
10%
0%
% Patients
6.8%
0%
*
% with anterior segment neovascularization by Week 24
Sham
2q4
*Compared to baseline; full analysis set; sham n=73, 2q4 n=114;
15


COPERNICUS
Quality of Life at 24 Weeks*
Change in NEI-VFQ Score
8
6
4
2
0
0.8
7.2*
N=59
N=104
Total Score^
Sham
2q4
*P = 0.001
vs. Sham
^Compared to baseline; full analysis set; sham n=59; 2q4 n=104.
16


COPERNICUS
Quality of Life Subscales at 24 Weeks+
Total *
Near ^
Distance #
Dependence ±
Change in NEI-VFQ Score
10
8
6
4
2
0
-2
0.8
7.2
1.84
6.25
-0.64
6.09
1.13
7.13
Sham
2q4
*P = 0.001
^P = 0.071
#P = 0.032
±P = 0.083
vs. Sham
Compared to baseline; full analysis set; sham n=59; 2q4 n=104;


SAFETY

COPERNICUS

% Patients with Study Eye Ocular SAEs at Week 24

	Sham	VTE 2q4
n (safety analysis set)	74	114
# subjects with at least 1 AE	10 (13.5%)	4 (3.5%)
Vitreous Hemorrhage	4 (5.4%)	0
Neovascular Glaucoma	2 (2.7%)	0
Iris Neovascularization	2 (2.7%)	0
Retinal hemorrhage	2 (2.7%)	0
Visual acuity reduced	1 (1.4%)	1 (0.9%)
Retinal Artery Occlusion	0	1 (0.9%)
Retinal Tear	1 (1.4%)	0
Retinal Vein Occlusion	1 (1.4%)	0
Endophthalmitis	0	1 (0.9%)
Corneal Abrasion	0	1 (0.9%)

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Biocon Exhibit 1012 - Page 5154

COPERNICUS
Deaths through Week 24

Arm	Age/Sex	Day from 1st Injection to Death	Day from Last Injection to Death	Preferred Term with Fatal Outcome
Sham	74 Male	202	54	Arrhythmia
Sham	64 Female	32	3	Acute myocardial infarction

20

COPERNICUS
% Patients with APTC Events through Week 24

	Sham	VTE 2q4
N (safety analysis set)	74	114
Total	2 (2.7%)	0
Vascular Deaths	2 (2.7%)	0
MI	1	0
Stroke	0	0
Arrhythmia	1	0
Non Fatal MI	0	0
Non Fatal Stroke (ischemic)	0	0

21

COPERNICUS
Conclusions

Safety:

- VEGF Trap Eye was tolerated without evidence of negative ocular or systemic effects

Efficacy:

- Statistically significant difference in proportion of patients who have gained ≥ 3 lines (56.1% vs 12.3%)
- Statistically significant difference in mean BCVA by 21 letters (+17.3 letters vs -4.0)
- Statistically significant difference in retinal thickness (312.2 μm difference)
- Statistically significant difference in total NEI-VFQ score (+7.2 vs +0.8)
- Reduction in formation of iris neovascularization (NVI) (6.8% vs 0%)

22

COPERNICUS
One Year Analysis

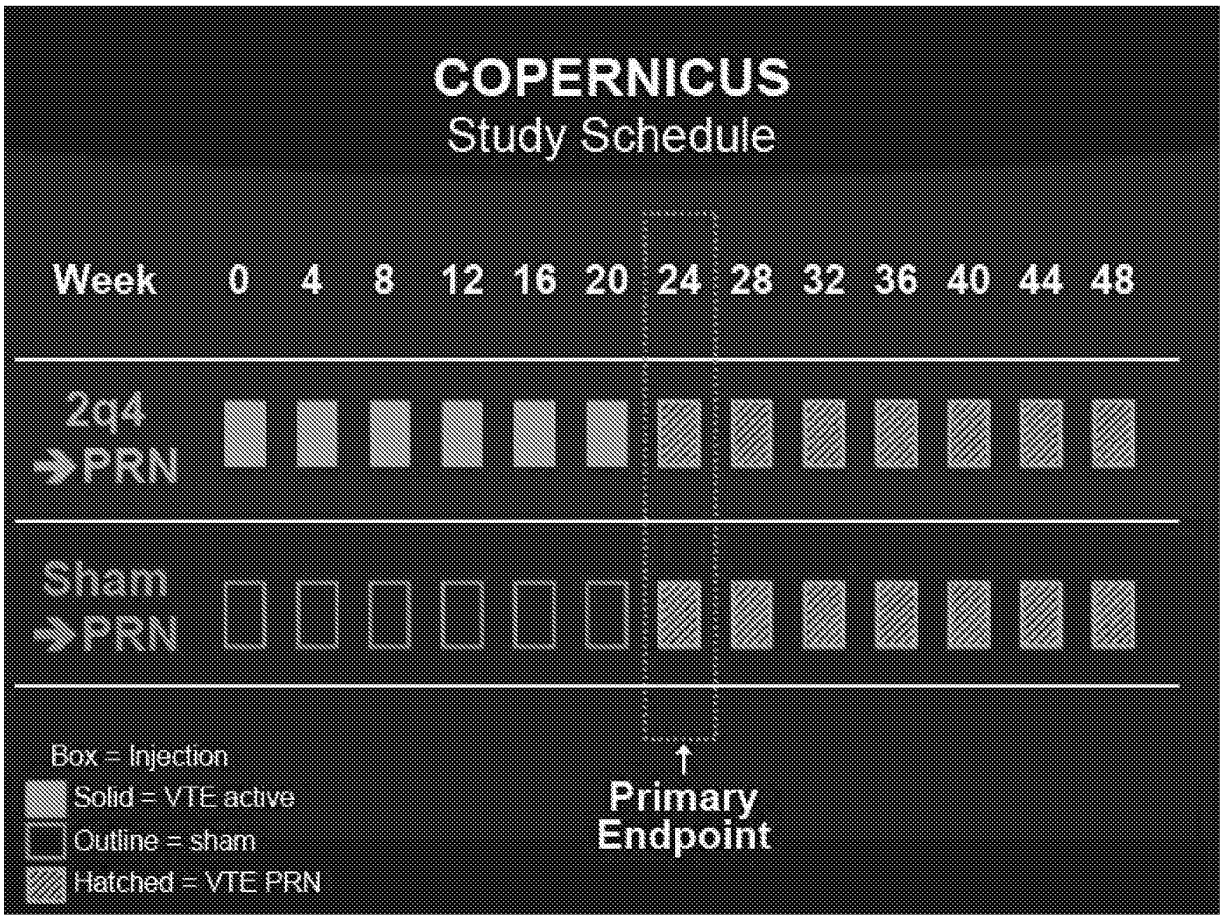
- After the primary endpoint at Week 24, all patients were eligible to receive VEGF Trap-Eye on a PRN basis

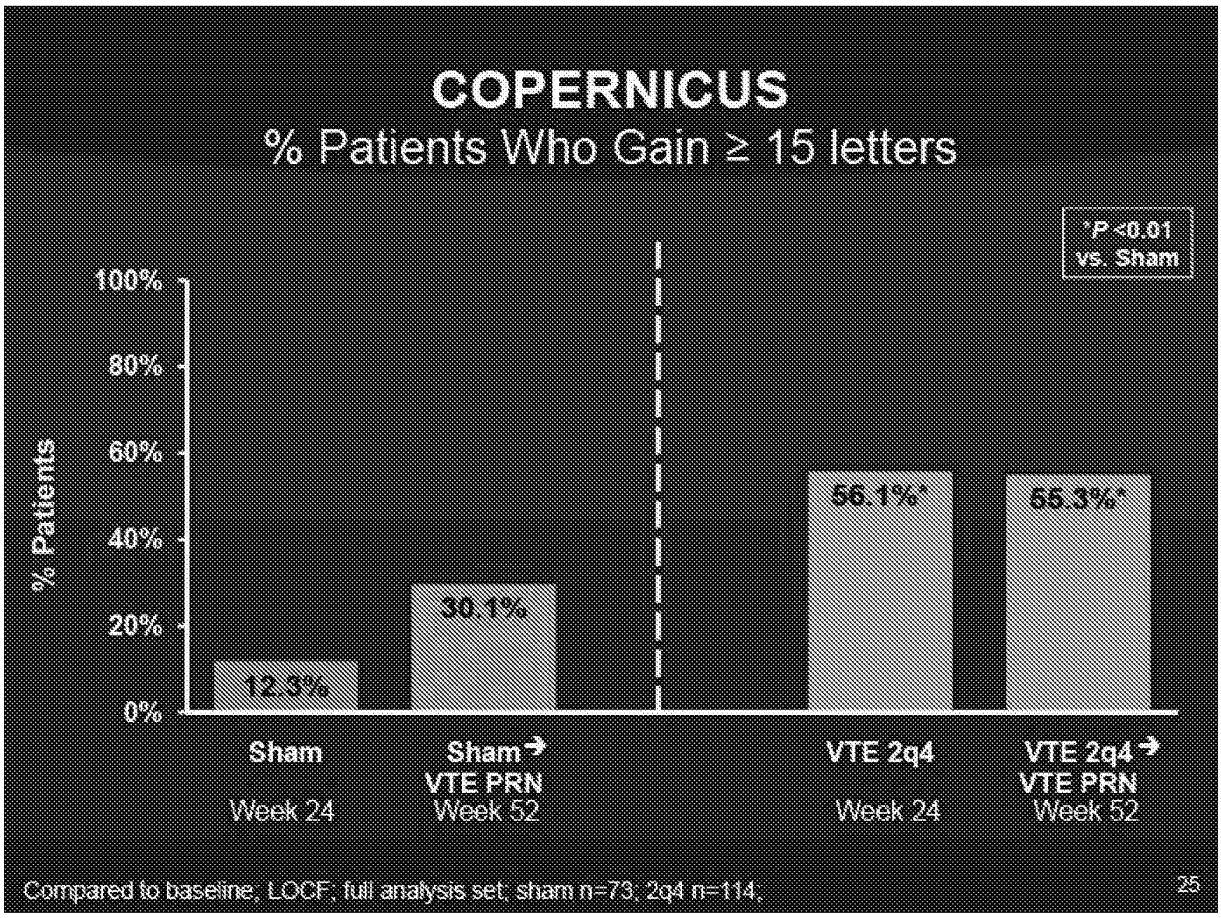
Sham → VTE PRN

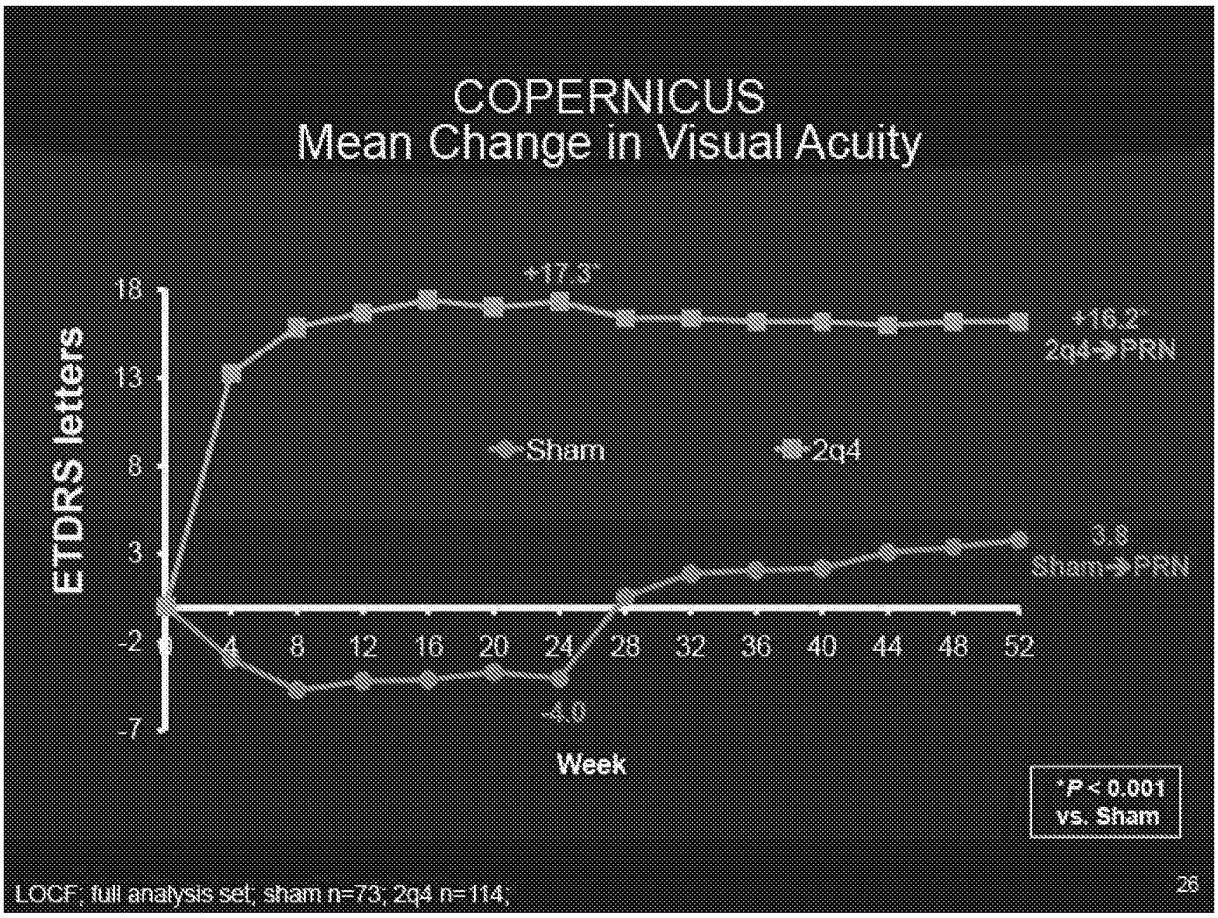
VTE 2q4 → VTE PRN

- Therefore, all but 3 patients in the sham arm who continued into the 2nd 6 months of the study received at least one dose of VEGF Trap-Eye

Samsung Bioepis Exhibit 1012 - Page 5158
Biocon Exhibit 1012 - Page 5158


COPERNICUS
Study Schedule
Week 0 4 8 12 16 20 24 28 32 36 40 44 48
2q4
PRN
Sham
PRN
Box = Injection
Solid = VTE active
Outline = sham
Hatched = VTE PRN
Primary
Endpoint


COPERNICUS
% Patients Who Gain ≥ 15 letters
*P <0.01
vs. Sham
100%
80%
60%
40%
20%
0%
% Patients
12.3%
30.1%
56.1%*
55.3%*
Sham
Week 24
Sham → VTE PRN
Week 52
VTE 2q4
Week 24
VTE 2q4 → VTE PRN
Week 52
Compared to baseline; LOCF; full analysis set; sham n=73; 2q4 n=114;
25


COPERNICUS
Mean Change in Visual Acuity
ETDRS letters
18
13
8
3
-2
-7
+17.3*
+16.2*
2q4→PRN
Sham
2q4
3.8
Sham→PRN
0
4
8
12
16
20
24
28
32
36
40
44
48
52
-4.0
Week
*P < 0.001
vs. Sham
LOCF; full analysis set; sham n=73; 2q4 n=114;
26

COPERNICUS
Retreatment Criteria

- > 50µm increase in CRT on OCT compared to lowest previous measurement
- New or persistent cystic retinal changes or sub-retinal fluid on OCT or persistent diffuse edema ≥ 250 µm in the central subfield on OCT
- Loss of ≥5 letters from the best previous measurement in conjunction with any increase in CRT on OCT
- An increase of ≥ 5 letters in visual acuity between the current and most recent visit

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COPERNICUS
Treatment Summary

Total PRN Injections (Week 24 to Week 52)

	Mean (SD)	Min:Max*	Median	Median time to first PRN injection
2q4 → VTE PRN (n = 110)	2.7 (1.7)	0:7	3.0	68
Sham → VTE PRN† (n = 60)	3.9 (2.0)	0:7	4.0	29

*Maximum of 7 injections possible
†3 Patients in the sham arm did not get treated with VTE during the 2nd 6 months

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Biocon Exhibit 1012 - Page 5163

COPERNICUS
% Patients with Study Eye Ocular SAEs

	Sham BL - Wk 24	Sham → VTE PRN Wk 24 - 52	VTE 2q4 BL - Wk 24	VTE 2q4 → VTE PRN Wk 24 - 52
n (safety analysis set)	74	60	114	110
# subjects w/ ≥ 1 AE	10 (13.5%)	2 (3.3%)	4 (3.5%)	3 (2.7%)
Cataract	0	1 (1.7%)	0	1 (0.9%)
Retinal Hemorrhage	2 (2.7%)	0	0	0
Visual Acuity Reduced	1 (1.4%)	0	1 (0.9%)	0
Vitreous haemorrhage	4 (5.4%)	1 (1.7%)	0	1 (0.9%)
Cystoid macular edema	0	0		1 (0.9%)
Glaucoma	2 (2.7%)	1 (1.7%)	0	0
Iris Neovascularization	2 (2.7%)	0	0	0
Retinal tear	1 (1.4%)	1 (1.7%)	0	0
Retinal vein occlusion	1 (1.4%)	0	0	1 (0.9%)
Retinal Artery occlusion	0	0	1 (0.9%)	0
Endophthalmitis	0	0	1 (0.9%)	0
Corneal Abrasion	0	0	1 (0.9%)	0

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COPERNICUS

% Patients with APTC Events

	Sham BL - Wk 24	Sham → VTE PRN Wk 24 - 52	VTE 2q4 BL - Wk 24	VTE 2q4 → VTE PRN Wk 24 - 52
N (safety analysis set)	74	60	114	110
Total	2 (2.7%)	0	0	1 (0.5%)
Vascular Deaths	2 (2.7%)	0	0	0
MI	1	0	0	0
Stroke	0	0	0	0
Arrhythmia	1	0	0	0
Non Fatal MI	0	0	0	1
Non Fatal Stroke (ischemic)	0	0	0	0

30

COPERNICUS
One-Year Conclusions

- Efficacy maintained to Week 52 with less frequent dosing
  - 55% of 3 line gainers for VTE/PRN vs. 30% for Sham/PRN
  - Mean change of BCVA at week 52 within 1 letter of week 24 outcome in the original 2q4 group
- Safety
  - VTE was generally well tolerated
  - Most common ocular adverse events were typical of those associated with intravitreal injections
  - Events associated with disease progression more frequent in the sham group

Samsung Bioepis Exhibit 1012 - Page 5166
Biocon Exhibit 1012 - Page 5166

Lexis® Securities Mosaic®

Company: REGENERON PHARMACEUTICALS INC

Form Type: 8-K

Filing Date: 11/21/2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 18, 2011 (November 18, 2011)

REGENERON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

New York	**000-19034**	**13-3444607**
(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

(914) 347-7000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On November 18, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration approved EYLEA™ (aflibercept) Injection for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Announcing FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011.

SIGNATURES

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 hereunto duly authorized.

Date: November 18, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa

Name:Joseph J. LaRosa

Title:Senior Vice President, General Counsel and Secretary

Exhibit Index

Number	Description
99.1	Press Release Announcing FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011

REGENERON

For Immediate Release

Press Release

Regeneron Announces FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration

EYLEA is the only FDA-approved treatment for wet AMD labeled for less than monthly dosing that demonstrated clinical equivalence to the monthly standard of care

Regeneron to host conference call on November 18, at 6:30 p.m. Eastern Time

Tarrytown, NY (November 18, 2011) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD) at a recommended dose of 2 milligrams (mg) every four weeks (monthly) for the first 12 weeks, followed by 2 mg every eight weeks (2 months).

The approval of EYLEA was granted under a Priority Review, a designation that is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. This approval was based upon the results of two Phase 3 clinical studies. In these studies, EYLEA dosed every eight weeks, following three initial monthly injections, was clinically equivalent to the standard of care, Lucentis® (ranibizumab injection) dosed every four weeks, as measured by the primary endpoint of maintenance of visual acuity (less than 15 letters of vision loss on an eye chart) over 52 weeks. The most common adverse reactions (frequency of 5% or more) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure. The adverse event profile was similar to that seen with ranibizumab.

"The approval of EYLEA offers a much needed new treatment option for patients with wet AMD," said Jeffrey Heier, M.D., a clinical ophthalmologist and retinal specialist at Ophthalmic Consultants of Boston, Assistant Professor of Ophthalmology at Tufts School of Medicine, and Chair of the Steering Committee for the VIEW 1 trial. "EYLEA offers the potential of achieving the efficacy we've come to expect from current anti-VEGF agents, but with less frequent injections and no monitoring requirements. This may reduce the need for costly and time-consuming monthly office visits for patients and their caregivers."

"This approval is an important step forward for Regeneron and for patients suffering with wet AMD, the most common cause of blindness in the U.S. in older adults," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We thank the patients and clinical investigators who participated in our clinical studies, the FDA, and the Regeneron employees who helped make this day possible. Now that EYLEA is approved, we plan to make EYLEA available to patients within the next few days."

About EYLEA™ (aflibercept) Injection
Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet age-related macular degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results.

EYLEA, known in the scientific literature as VEGF Trap-Eye, is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors.

EYLEA is indicated for the treatment of patients with neovascular age-related macular degeneration (wet AMD). EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

The recommended dose for EYLEA is 2 mg administered by intravitreal injection every four weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every eight weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every four weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every four weeks compared to every eight weeks.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs with EYLEA in clinical trials was low (1.8%) .

Serious adverse reactions related to the injection procedure have occurred in less than 0.1% of intravitreal injections with EYLEA and include endophthalmitis, traumatic cataract, and increased intraocular pressure.

About the VIEW 1 and VIEW 2 Clinical Studies

The safety and efficacy of EYLEA were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with EYLEA) in the two studies (VIEW 1 and VIEW 2). In each study, patients were randomly assigned in a 1:1:1:1 ratio to one of four dosing regimens: 1) EYLEA administered 2 mg every eight weeks following three initial monthly doses (EYLEA 2Q8); 2) EYLEA administered 2 mg every four weeks (EYLEA 2Q4); 3) EYLEA 0.5 mg administered every four weeks (EYLEA 0.5Q4); and 4) ranibizumab administered 0.5 mg every four weeks (ranibizumab 0.5Q4) . Patient ages ranged from 49 to 99 years with a mean of 76 years.

In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of visual acuity at week 52 compared to baseline. Data are available through week 52. Both the EYLEA™ (aflibercept) Injection 2Q8 and 2Q4 dosing groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5Q4 group for the primary endpoint.

Select results of the VIEW 1 and VIEW 2 studies as described in the full Prescribing

Information for the EYLEA 2 mg every four weeks and EYLEA 2 mg every eight weeks dosing groups as compared to ranibizumab dosed monthly group are shown below.

Efficacy Outcomes at Week 52 (Full Analysis Set with LOCF) in VIEW 1 and VIEW 2 Studies

	VIEW 1			VIEW 2		
	EYLEA 2 mg Q8 weeks[a]	EYLEA 2 mg Q4 weeks	ranibizu-mab 0.5 mg Q4 weeks	EYLEA 2 mg Q8 weeks[a]	EYLEA 2 mg Q4 weeks	ranibizu-mab 0.5 mg Q4 weeks
Full Analysis Set	N=301	N=304	N=304	N=306	N=309	N=291
Efficacy Outcomes						
Proportion of patients who maintained visual acuity (%) (<15 letters of BCVA loss)	94%	95%	94%	95%	95%	95%
Difference[b] (%) (95.1% CI)	0.6 (-3.2, 4.4)	1.3 (-2.4, 5.0)		0.6 (-2.9, 4.0)	-0.3 (-4.0, 3.3)	
Mean change in BCVA as measured by ETDRS letter score from Baseline	7.9	10.9	8.1	8.9	7.6	9.4
Difference[b] in LS mean (95.1% CI)	0.3 (-2.0, 2.5)	3.2 (0.9, 5.4)		-0.9 (-3.1, 1.3)	-2.0 (-4.1, 0.2)	

BCVA = Best Corrected Visual Acuity; CI = Confidence Interval; ETDRS = Early Treatment Diabetic Retinopathy Study; LOCF = Last Observation Carried Forward (baseline values are not carried forward); 95.1% confidence intervals were presented to adjust for safety assessment conducted during the study.

[a] After treatment initiation with 3 monthly doses

[b] EYLEA group minus the ranibizumab group

IMPORTANT SAFETY INFORMATION

EYLEA™ (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs with EYLEA in clinical trials was low (1.8%) .

Serious adverse reactions related to the injection procedure have occurred in less than 0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, and increased intraocular pressure.

The most common adverse reactions (greater than or equal to 5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Please see the full Prescribing Information for EYLEA, available online at www.regeneron.com/EYLEA-fpi.pdf.

About the EYLEA™ (aflibercept) Injection Global Collaboration
Regeneron is collaborating with Bayer HealthCare on the global development of EYLEA. Bayer submitted an application for marketing authorization in Europe for wet AMD in June 2011.

Bayer HealthCare will market EYLEA outside the United States, where the companies will share equally the profits from any future sales of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States.

About Wet AMD
Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating distortion and/or blind spots in central vision. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

Conference Call Information
Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron, and other members of senior management will host a conference call to discuss the FDA approval of EYLEA for the treatment of patients with wet AMD and launch plans, as well as other corporate matters. The interactive call will be held on November 18, 2011 at 6:30 p.m. Eastern Time and can be accessed live through the Regeneron website at www.regeneron.com on the Investor Relations page. The call, including the question and answer session, can also be accessed by dialing:

Domestic Dial-in Number: (888) 660-6127

International Dial-in Number: (973) 890-8355

Participant Passcode: 30193445

An archived version of the conference call will be available for 30 days on the company's website at www.regeneron.com on the Investor Relations page.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA™ (aflibercept) Injection. Regeneron also has completed several Phase 3 studies and is conducting an additional Phase 3 clinical trial for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on the Regeneron web site at www.regeneron.com.

Regeneron Forward Looking Statement
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of EYLEA and Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA and other products and drug candidates, competing drugs that may be superior to EYLEA and Regeneron's products and drug candidates, uncertainty of market acceptance of EYLEA and Regeneron's products and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended September 30, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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STACK:

/quit
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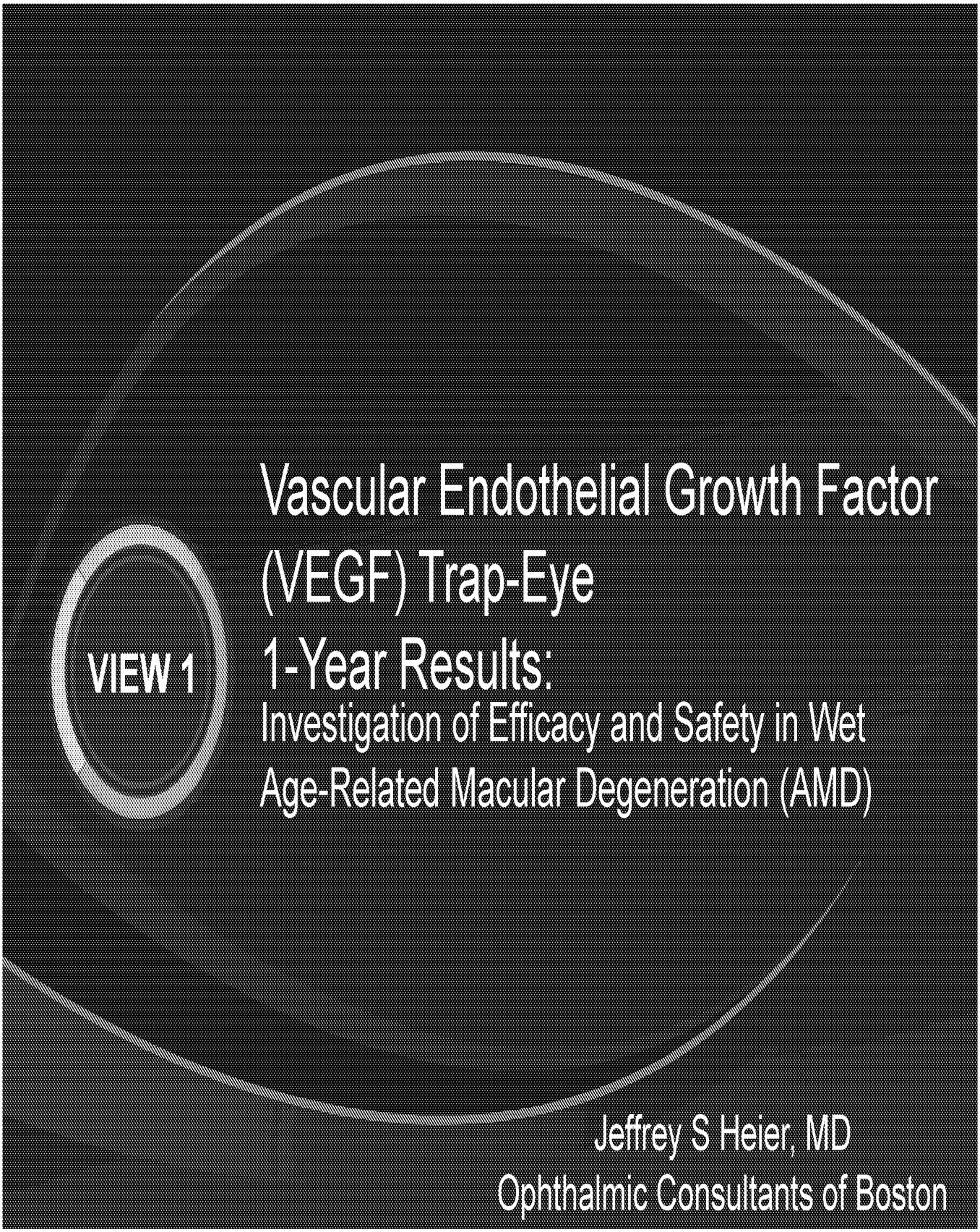
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-mark-
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VIEW 1
Vascular Endothelial Growth Factor (VEGF) Trap-Eye
1-Year Results:
Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD)
Jeffrey S Heier, MD
Ophthalmic Consultants of Boston

Financial Disclosure

- Scientific Advisor:

  Alcon, Genentech, Genzyme, GlaxoSmithKline, LPath, Neovista, Oraya, Paloma, Regeneron, Sequenom

- Research Support:

  Alcon, Genentech, Genzyme, GlaxoSmithKline, Neovista, Ophthotech, Regeneron

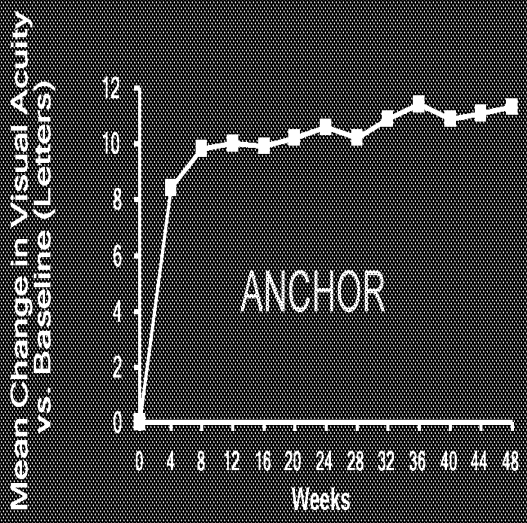
Introduction

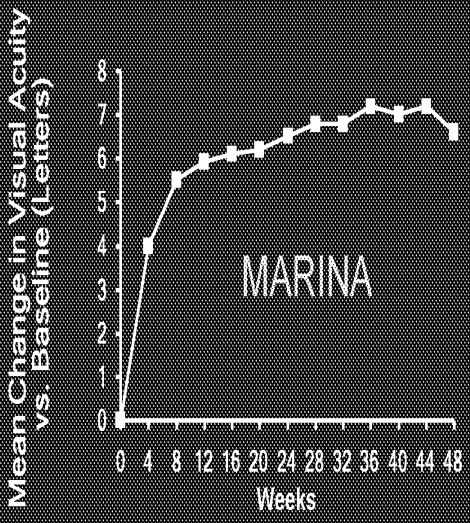
- Anti-VEGF therapy has led to dramatic advances in the treatment of exudative AMD
  - The large majority of patients are stabilized
  - Significant visual gain in **25-40%**
- Such outcomes appear to be dependent upon frequent injections over prolonged periods
  - Attempts at reducing the treatment burden often lead to less robust outcomes

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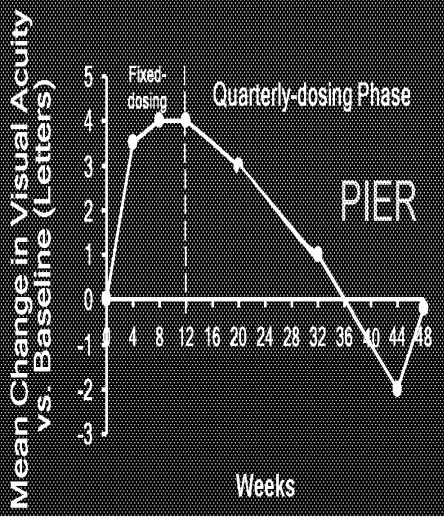
The Dilemma With Anti-VEGF Treatment

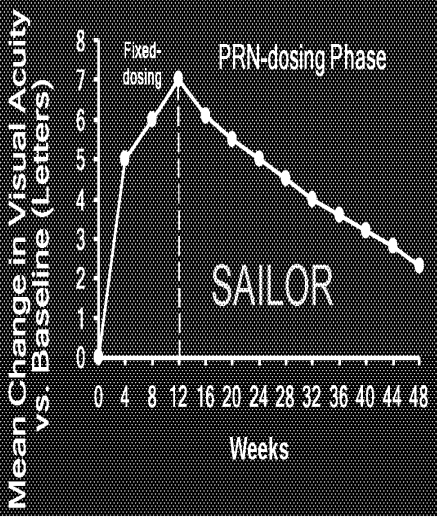
Vision gains maintained with monthly dosing





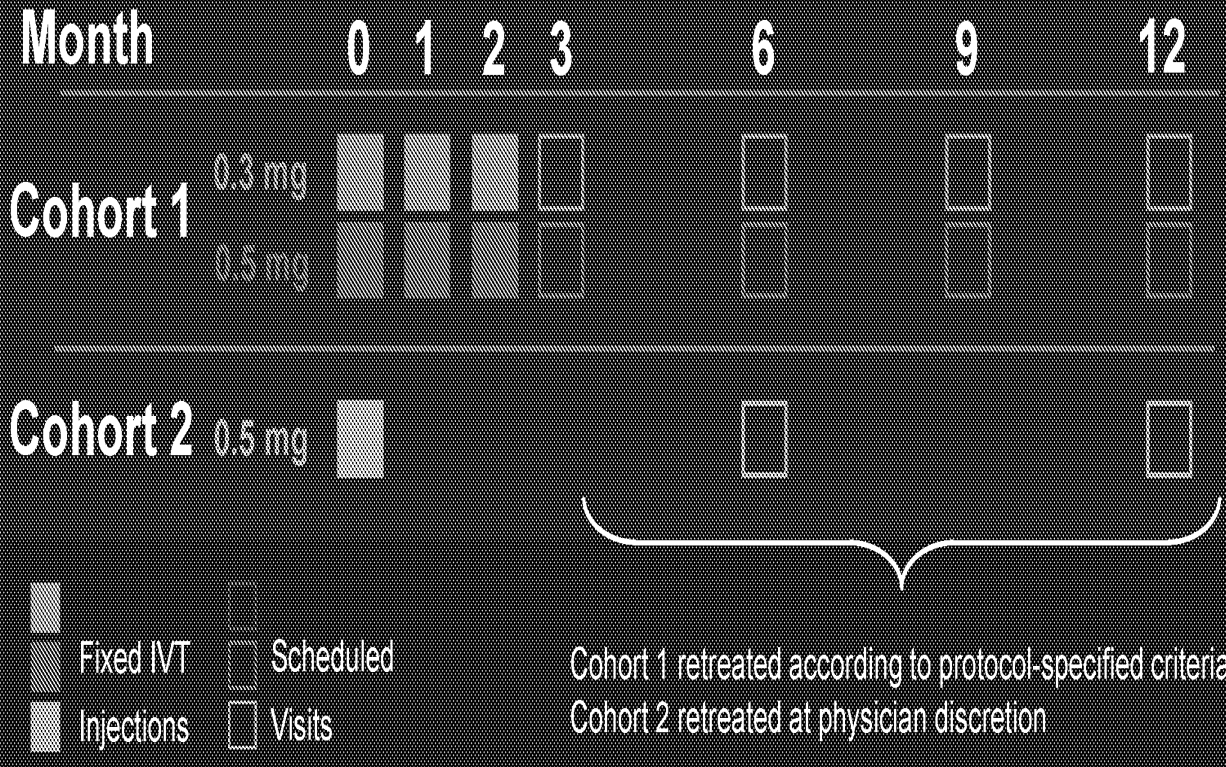
Vision gains appear to diminish with less frequent dosing





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SAILOR
Treatment and Assessments



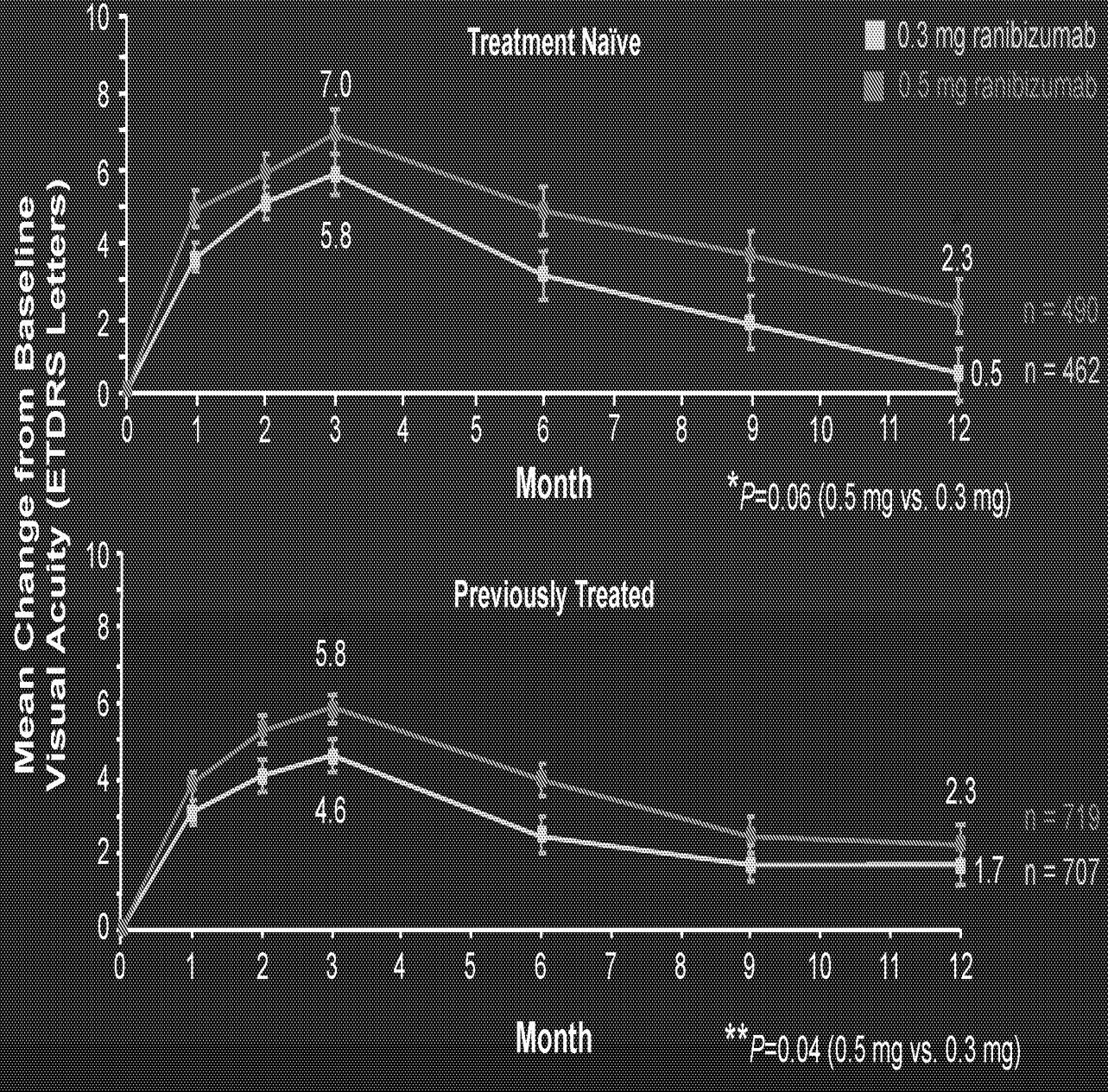
Fixed IVT Injections

Scheduled Visits

Cohort 1 retreated according to protocol-specified criteria*
Cohort 2 retreated at physician discretion

*VA (>5 letter decrease in VA from highest VA at prior visits) *or* VA *and/or* OCT (>100 µm increase in central foveal thickness from lowest measurement at prior visits).

Change from Baseline Visual Acuity
(Cohort 1)



The last observation carried forward method was used for missing VA data.
Error bars are ± 1 standard error of the mean.

Not a New Concept

Year 2 Efficacy Results of 2 Randomized Controlled Clinical Trials of Pegaptanib for Neovascular Age-Related Macular Degeneration

VEGF Inhibition Study in Ocular Neovascularization (V.I.S.I.O.N.) Clinical Trial Group*

Objective: To evaluate the efficacy of a second year of pegaptanib sodium therapy in patients with neovascular age-related macular degeneration (AMD).

Design: Two concurrent, multicenter, randomized, double-masked, sham-controlled studies (Veterans Administration Study in Ocular Neovascularization [V.I.S.I.O.N.] Clinical Trial Group; Macular Endothelial Growth Factor Inhibition Study in Ocular Neovascularization) trials.

Participants: Patients with all angiographic neovascular lesion compositions of AMD were enrolled. In combined analyses, 88% (1003/1190) were re-randomized at week 54, and 80% (951/1200) were assessed at week 102.

Interventions: At week 54, those initially assigned to pegaptanib were re-randomized 1:1 to continue or discontinue therapy or 18 more weeks (8 injections). Those initially assigned to sham were re-randomized to continue sham, discontinue sham, or receive 1 of 3 pegaptanib doses.

Main Outcome Measures: Mean change in visual acuity (VA) over time and mean change in the standardized area under the curve of VA and proportions of patients experiencing a loss of ≥15 letters from week 54 to week 102; losing <15 letters (maintaining) from baseline to week 102; gaining ≥0, ≥1, ≥2, and ≥3 lines of VA; and progressing to legal blindness (20/200 or worse).

Results: In combined analysis, mean VA was maintained in patients continuing with 0.3-mg pegaptanib compared with those discontinuing therapy or receiving usual care. In patients who continued pegaptanib, the proportion who lost ≥15 letters from baseline in the period from week 54 to week 102 was 22% (vs. 55% for all patients who discontinued pegaptanib or remained on usual care; $P<0.001$ for each). Kaplan–Meier analysis showed that patients continuing 0.3-mg pegaptanib for a second year were less likely to lose ≥15 letters than those re-randomized to discontinue after 1 year ($P<0.001$). The proportion of patients gaining ≥0 letters was higher for those assigned to 2 years of 0.3-mg pegaptanib than receiving usual care. Progression to legal blindness was reduced for patients continuing 0.3-mg pegaptanib for 2 years.

Conclusions: Continuing visual benefit was observed in patients who were randomized to receive therapy with pegaptanib in year 2 of the V.I.S.I.O.N. trials when compared with 2 years' usual care or cessation of therapy at year 1. Ophthalmology 2006;113:1508–1525 © 2006 by the American Academy of Ophthalmology.

From a worldwide perspective, age-related macular degeneration (AMD) has been estimated to cause 8.7% of total blindness.[1] In the United Kingdom, 2.5% of individuals ≥75 years of age were legally impaired due to AMD.[2] It has been estimated that in the United States as many as 15 million people suffer from some form of AMD,[3] with more than 1.6 million experiencing the active blood vessel growth and leakage associated with neovascular AMD.[4] Many studies have shown that two thirds of eyes with this disorder have experienced moderate or severe vision loss within 2 years of inception.[5–7]

The presence of vascular endothelial growth factor (VEGF), particularly the $VEGF_{165}$ isoform, has been implicated as a key mediator in the pathogenesis of blood vessel growth and leakage, both hallmarks of neovascular AMD. A glycoprotein growth factor, VEGF stimulates blood vessel growth by promoting endothelial cell proliferation and survival,[8,9] mobilizing bone marrow–derived endothelial cell precursors,[10,11] upregulating the synthesis of enzymes that degrade the extracellular matrix, and increasing blood vessel permeability.[12,13] Vascular endothelial growth factor

Originally received: November 30, 2005.
Accepted: February 10, 2006. Manuscript no. 2005-1091.

Consultants: see appendix.
Correspondence: see appendix.

Poster results presented at: Association for Research in Vision and Ophthalmology Annual Meeting, May 2005, Fort Lauderdale, Florida.
Study supported by Pfizer Pharmaceuticals, Inc., New York, New York, and Eyetech, Inc., New York, New York.

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doi:10.1016/j.ophtha.2006.05.031
0161-6420/06/$–see front matter

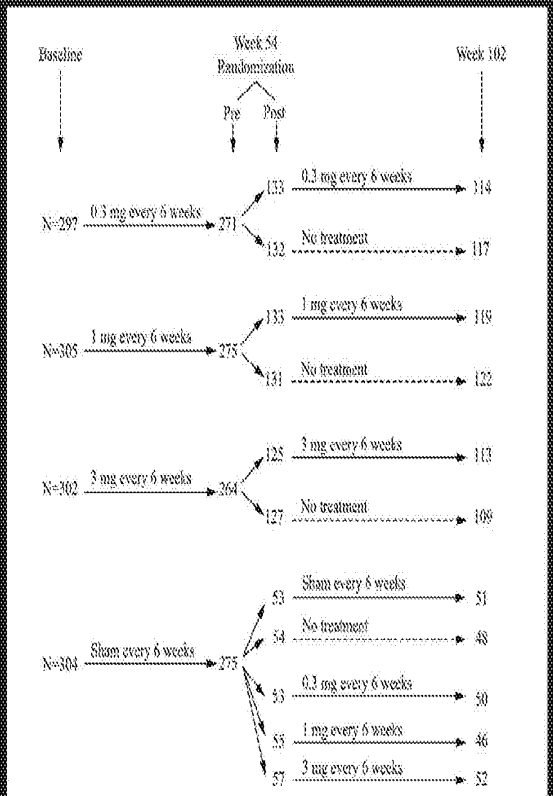


Figure 1. Number of patients randomized and assessed. Post = after; pre = before.

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Benefit of Continued Treatment

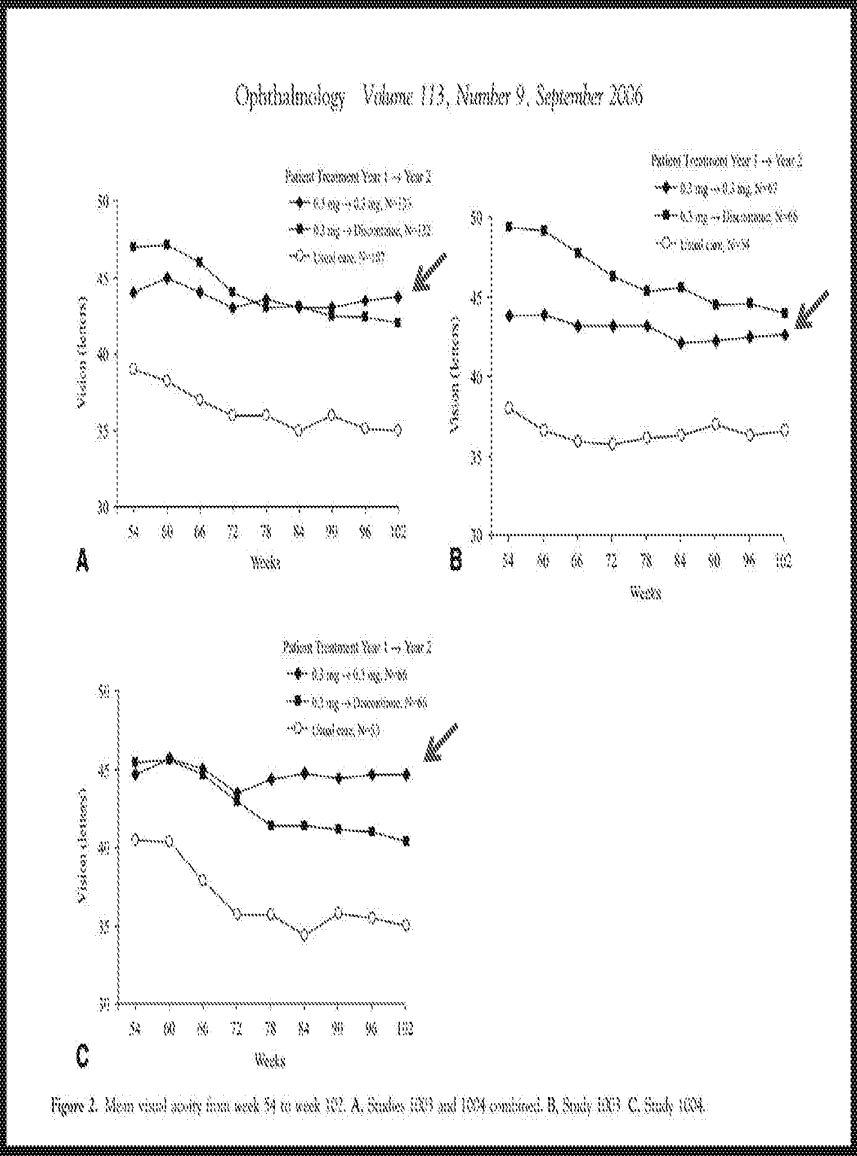
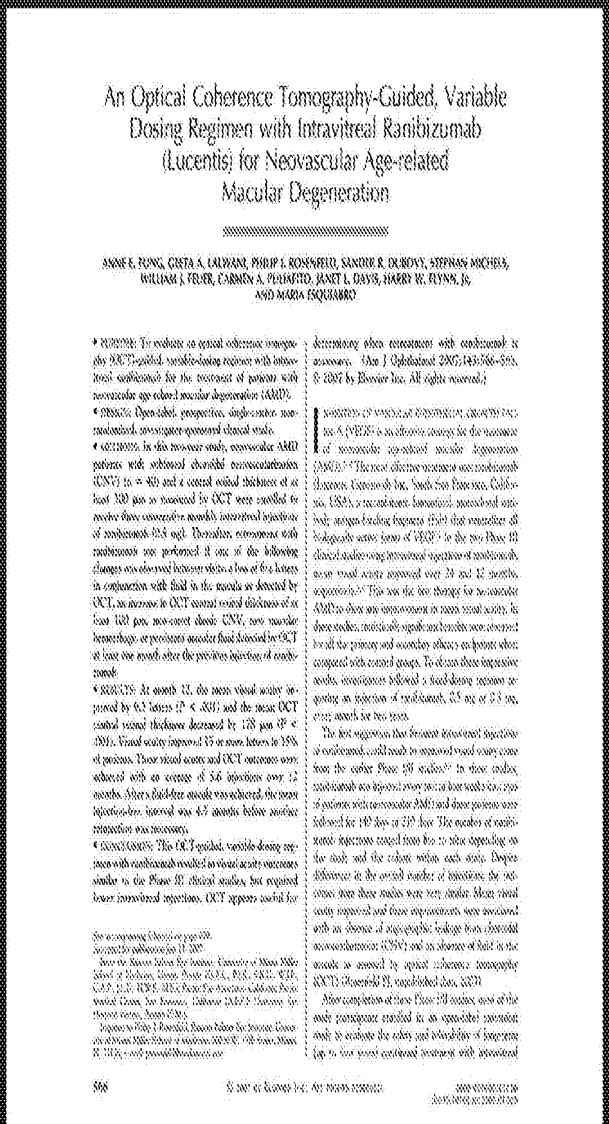


Figure 2. Mean visual acuity from week 54 to week 102. A, Studies 1026 and 1027 combined. B, Study 1025. C, Study 1028.

"The V.I.S.I.O.N. trials showed that 2 years' continued VEGF165 inhibition with pegaptanib provided patients with the best chance of preserving vision"

Can Variable Dosing Lead to Significant Visual Gain?



An Optical Coherence Tomography-Guided, Variable Dosing Regimen with Intravitreal Ranibizumab (Lucentis) for Neovascular Age-related Macular Degeneration

ANNE E. FUNG, GRETA A. LALWANI, PHILIP J. ROSENFELD, SANDER R. DUBOVY, STEPHAN MICHELS, WILLIAM J. FEUER, CARMEN A. PULIAFITO, JANET L. DAVIS, HARRY W. FLYNN, JR, AND MARIA ESQUIABRO



A Variable-dosing Regimen with Intravitreal Ranibizumab for Neovascular Age-related Macular Degeneration: Year 2 of the PrONTO Study

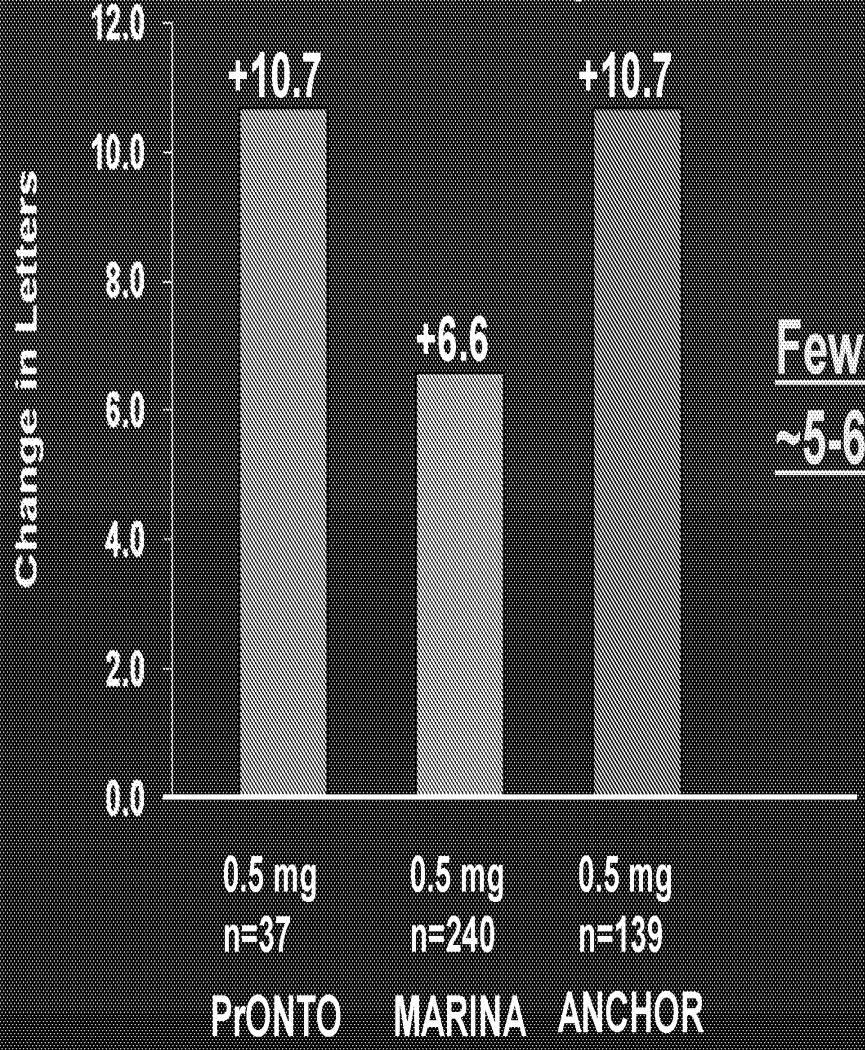
GRETA A. LALWANI, PHILIP J. ROSENFELD, ANNE E. FUNG, SANDER R. DUBOVY, STEPHEN MICHELS, WILLIAM FEUER, JANET L. DAVIS, HARRY W. FLYNN, JR, AND MARIA ESQUIABRO

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The PrONTO Study

Mean Change in Visual Acuity at Month 24

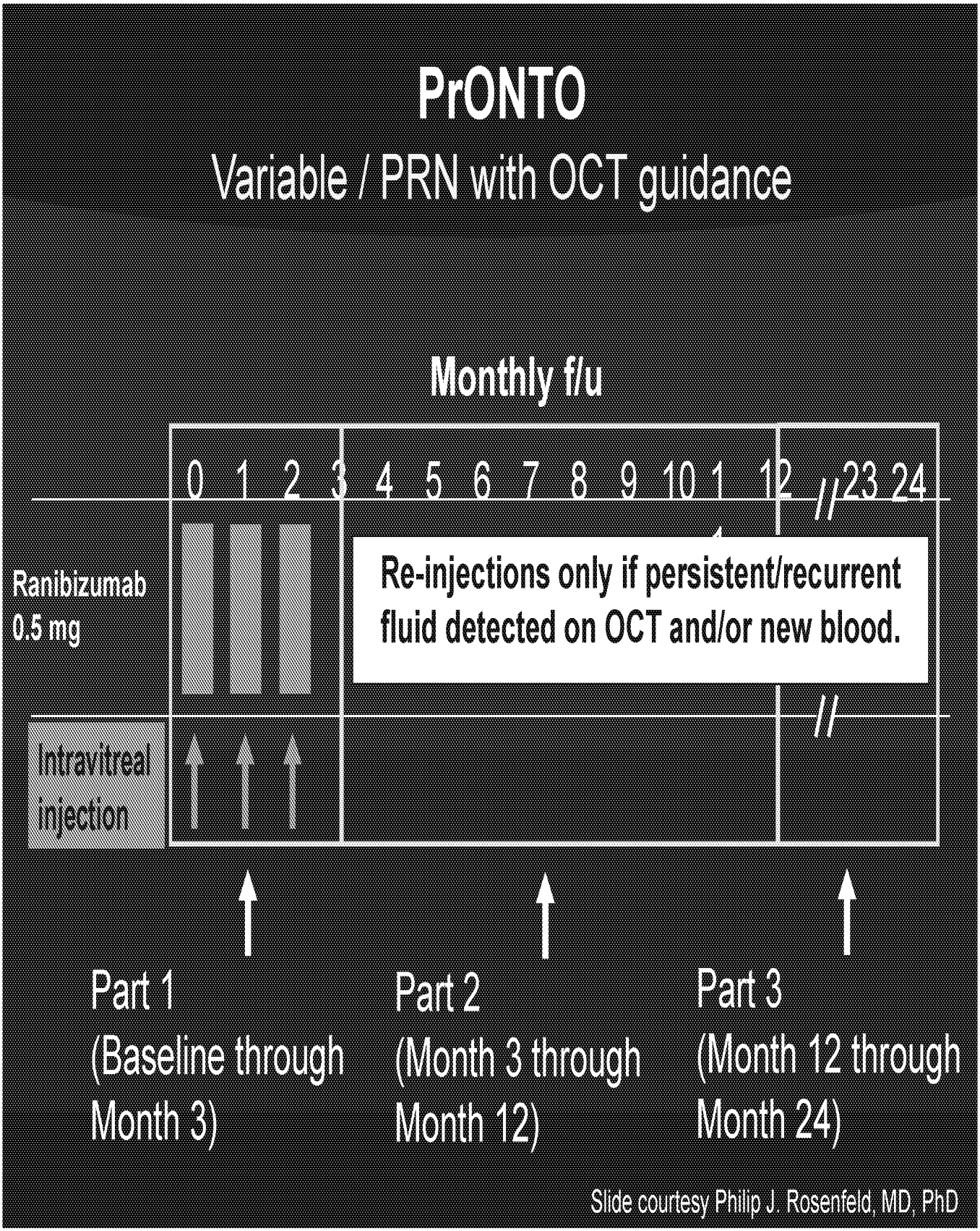
Comparison of PrONTO, MARINA, and ANCHOR Endpoints



Fewer injections

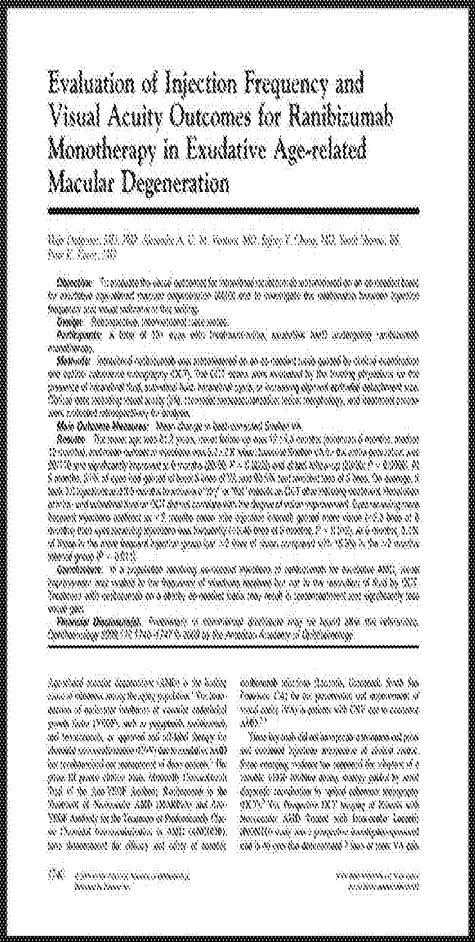
~5-6/year

Slide courtesy Philip J. Rosenfeld, MD, PhD


PrONTO
Variable / PRN with OCT guidance
Monthly f/u
0 1 2 3 4 5 6 7 8 9 10 1 12 //23 24
Ranibizumab
0.5 mg
Re-injections only if persistent/recurrent fluid detected on OCT and/or new blood.
Intravitreal injection
Part 1 (Baseline through Month 3)
Part 2 (Month 3 through Month 12)
Part 3 (Month 12 through Month 24)
Slide courtesy Philip J. Rosenfeld, MD, PhD

Real World Review

Retrospective review



Evaluation of Injection Frequency and Visual Acuity Outcomes for Ranibizumab Monotherapy in Exudative Age-related Macular Degeneration

Retrospective review



Results of One-Year's Treatment with Ranibizumab for Exudative Age-related Macular Degeneration in a Clinical Setting

- •Prevention of moderate vision loss obtained
- •"Far less" robust visual acuity gains

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Bad Things Can Come to Those Who Wait

MACULAR HEMORRHAGE IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION AFTER STABILIZATION WITH ANTIANGIOGENIC THERAPY

JONATHAN P. LEVINE, MD,[1] ANNA MARCUS, MD,[1]
JOHN A. ROBINSON, MD,[1] RICHARD F. SPAIDE, MD,[1]
MICHAEL J. COUSSENS, MD, MBA,[2] K. BAILEY FREUND, MD[1,3]

Purpose: To study patients with neovascular age-related macular degeneration (AMD) who experienced a macular hemorrhage after stabilization with intravitreal antivascular endothelial growth factor (anti-VEGF) injects to optimize current treatment regimens and prevent disease progression.

Methods: Retrospective chart review of six patients. The main outcome measures evaluated were outcomes after treatment with vEGF medication and area of hemorrhage, time between last office visit and date of hemorrhage, and visual acuity before and after hemorrhage.

Results: Three of 6 eyes had a macular hemorrhage within 4 weeks of a stable examination. One eye had optical coherence tomography (OCT) that demonstrated fluid 1 day before the macular hemorrhage. The average time between the time of the last injection and macular hemorrhage was 7.83 weeks (range, 1 day to 2.3 months). Three of six patients had a persistent decline in vision after the hemorrhage. Among the 4 patients who had better than 20/200 vision before the macular hemorrhage, 3 dropped to 20/200 or worse.

Conclusions: Hypertransmitting macular hemorrhages from AMD can occur within days to weeks after a stable examination and absence of fluid on OCT. Symptoms that herald "an impending" bleed are obvious beginning and OCT may not be appreciable for certain patients.

RETINA 20:474–478, 2000

Recombinant and conformant have been welcomed as breakthrough antiangiogenic therapies for the treatment of neovascular AMD.[1–3] The pivotal fifth analysis of randomized, double-masked trial of the efficacy of monthly intravitreal injections in improving visual outcomes in eyes with neovascular AMD for up to 2 years. More recently, the PRONTO trial, a small nonrandomized study, suggested that a variable dosing regimen, using OCT as a guide for re-treatment, could also achieve good visual results with the advantage of fewer treatments than a monthly dosing regimen.[4] Despite the efficacy of existing regimens, eight-week dosing intervals of macular evaluation remain a concern for the treating physician. Furthermore, although OCT has become the standard of care for monitoring patients receiving anti-VEGF therapy, it remains unproven whether OCT will reliably detect evidence of impending neovascular activity before a visually significant macular hemorrhage.

We present a case series of six eyes with neovascular AMD exhibited after intravitreal bevacizumab or ranibizumab treatment that subsequently developed a sight-threatening macular hemorrhage.

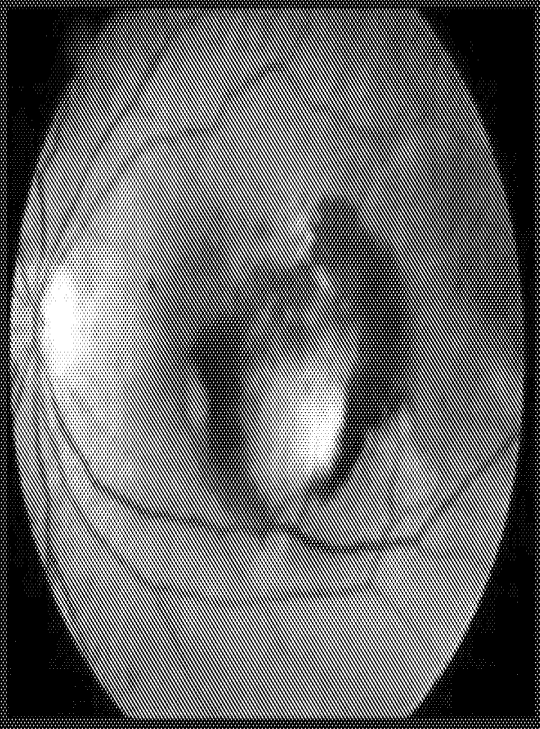
From the [1]Allen Eberle College of Medicine, Miami, New York, [2]New York University School of Medicine, Manhattan Eye, Ear & Throat Hospital, and [3]The Eberle F. Moore Retinal Research Center, Manhattan Eye, Ear, and Throat Hospital, New York, New York.

Supported in part by The Eberle F. Moore Retinal Research Center at the Manhattan Eye, Ear & Throat Hospital and The Macula Foundation, Inc.

Reprint requests: K. Bailey Freund, MD, Vitreous-Retina-Macula Consultants of New York, 460 Park Avenue, 9th Floor, New York, NY 10022; e-mail: vrmny@aol.com

Methods

We reviewed the records of 265 patients with a history of neovascular AMD at one clinical center



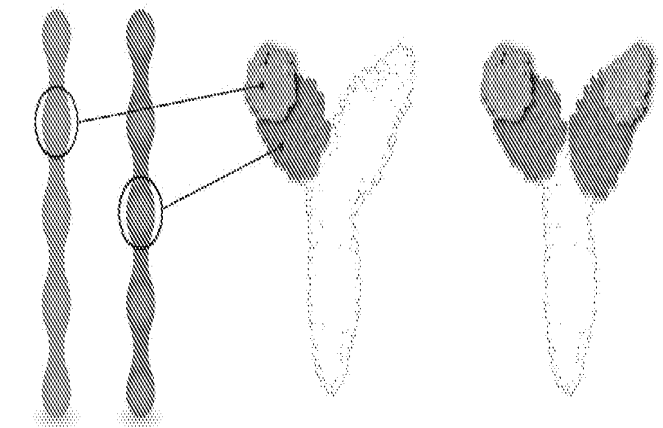
Samsung Bioepis Exhibit 1012 - Page 5195
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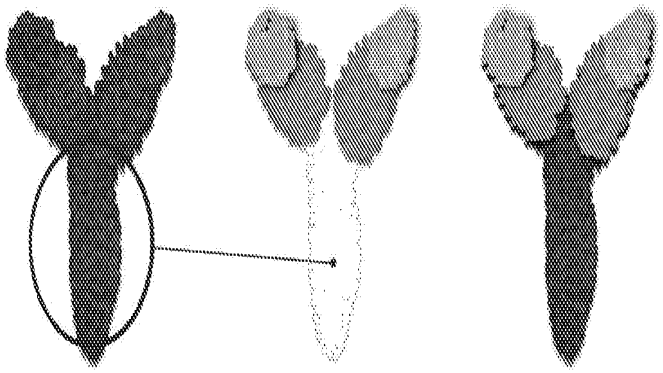
Submacular Hemorrhages during PRN Treatment

- 6 eyes stabilized with anti-VEGF therapy
- No sign of neovascular activity on exam or OCT
- Average time between hemorrhage and last injection: 16 weeks (range 7-29)
- Average time between hemorrhage and last examination: 4 weeks (range 1 day-7 weeks)
  - 3/6 had a hemorrhage within 4 weeks
  - 1 patient had a fluid-free OCT 1 day earlier

Samsung Bioepis Exhibit 1012 - Page 5196
Biocon Exhibit 1012 - Page 5196

VEGF Trap-Eye:
Specifically Designed to Block Members of the VEGF Family





- **Fusion protein** of key domains from human VEGF receptors 1 and 2 with human IgGFc
- **Blocks all VEGF-A** isoforms and placental growth factor **(PlGF)**
- **High affinity** - binds VEGF-A and PlGF more tightly than native receptors
- Contains **all human** amino acid sequences
- VEGF Trap-Eye is **specially purified and formulated** for intravitreal injection

IgG=immunoglobulin G

VEGF Trap-Eye Binding



VEGF Trap-Eye Potently Blocks VEGF-A and Uniquely Binds PlGF

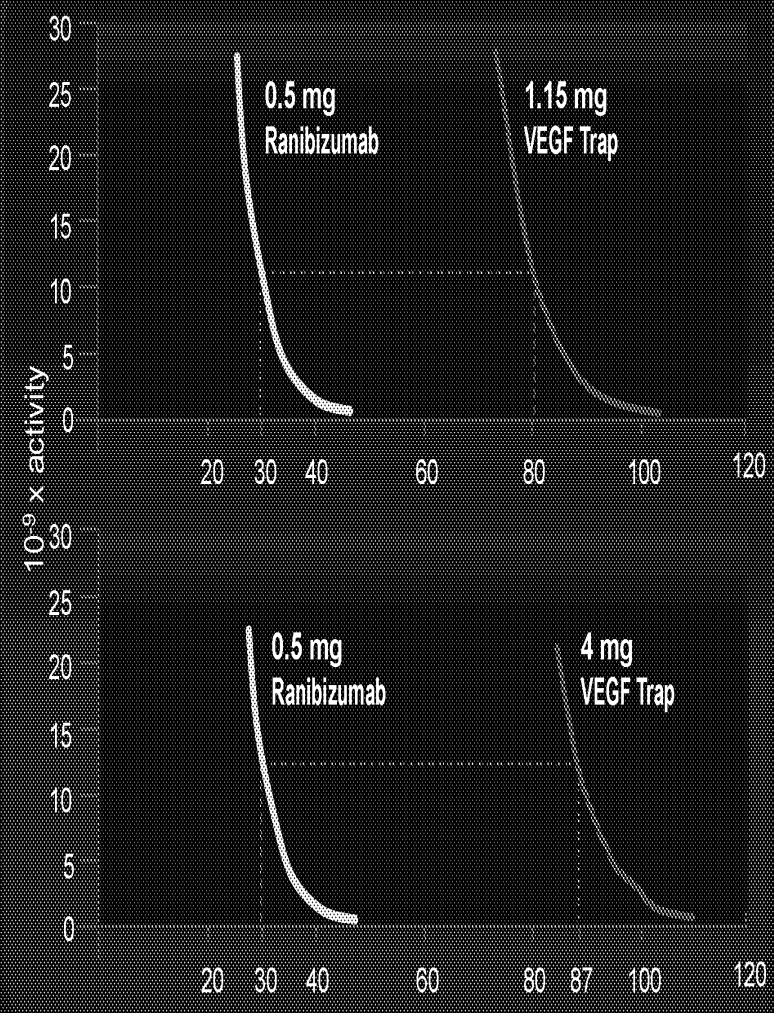
	VEGFR1 cell line			VEGFR2 cell line	
	IC_{50} at 20pM $VEGF\text{-}A_{121}$	IC_{50} at 20pM $VEGF\text{-}A_{165}$	IC_{50} at 40pM hPlGF2	IC_{50} at 20pM $VEGF\text{-}A_{121}$	IC_{50} at 20pM $VEGF\text{-}A_{165}$
VEGF Trap	15 pM	16 pM	2890 pM	15 pM	26 pM
bevacizumab	854pM	1476 pM	NB	706 pM	1323 pM
ranibizumab	675 pM	1140 pM	NB	686 pM	845 pM

NB: no detectable blocking under the assay conditions used

Data on file, Regeneron Pharmaceuticals, Inc.

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Biocon Exhibit 1012 - Page 5199

Modeling of Prolonged Biological Activity of Intravitreal VEGF Trap-Eye



VEGF Trap 1.15mg at 79 days ≅ ranibizumab 0.5mg at 30 days*

VEGF Trap 4mg at 87 days ≅ ranibizumab 0.5mg at 30 days*

*By extrapolation, VEGF Trap-Eye 2 mg at 83 days ≅ ranibizumab 0.5mg at 30 days**

MW Stewart, PJ Rosenfeld Br J *Ophthalmol* 2008;92:667–668.

*Est. biologic activity

Samsung Bioepis Exhibit 1012 - Page 5200
Biocon Exhibit 1012 - Page 5200

Potential Role of PlGF in Angiogenesis

Placental Growth Factor (PlGF)-Deficient Mice Show Delays in Normal Retinal Vascular Development and Reduced Vascular Abnormalities in Oxygen-Induced Retinal Ischemia

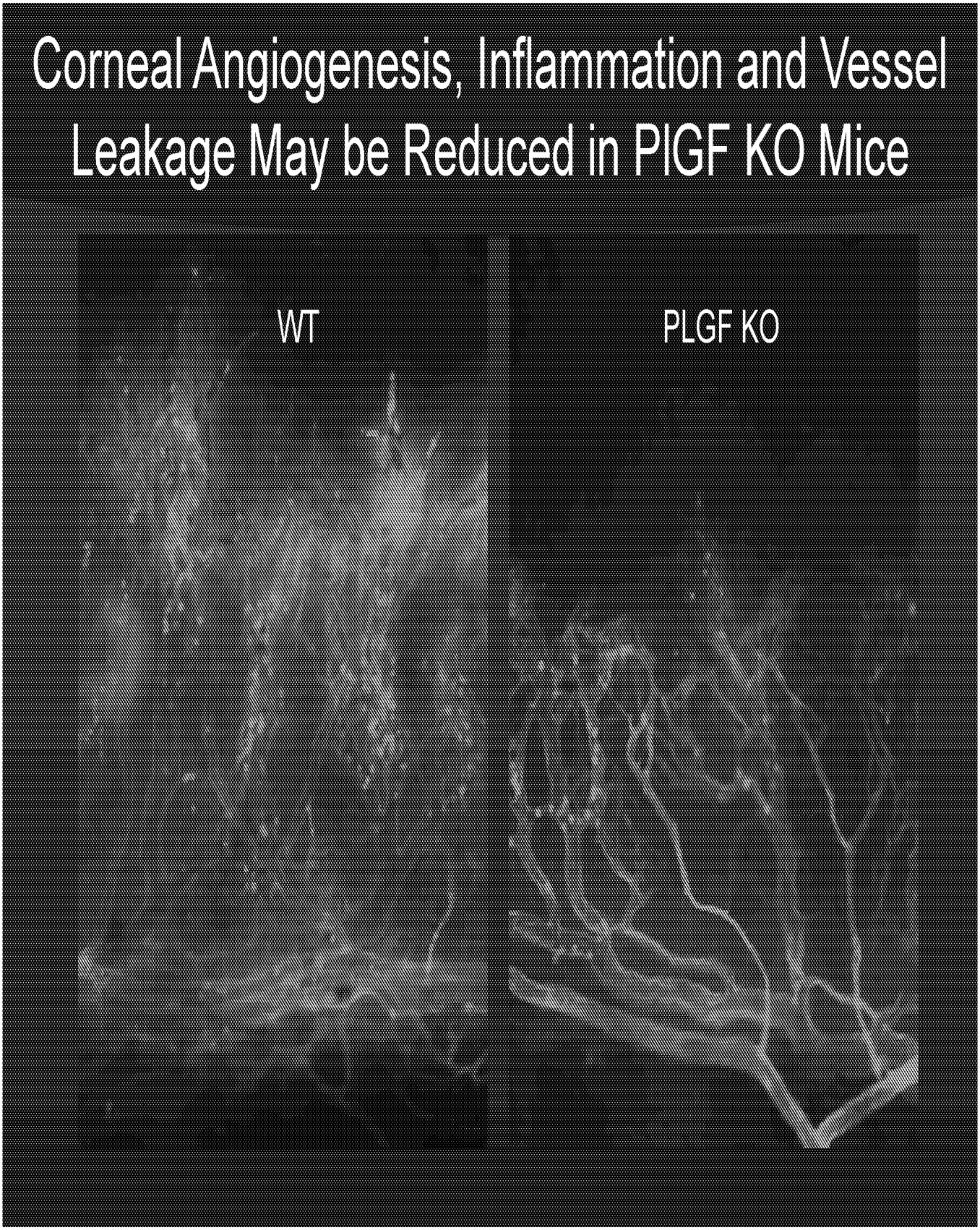
E. Cheung, K. Myers, G.D. Yancopoulos, I.B. Lobov, S.J. Wiegand.
Ophthalmology, Regeneron Pharmaceuticals, Tarrytown, NY

ARVO, 2009 Poster # A462

Conclusion:

This study establishes a role for PlGF in normal retinal vascular development, as well as in the response to retinal ischemia. ***These results are consistent with observations in other disease models, which suggest that PlGF inhibition may ameliorate pathological angiogenesis.***

Corneal Angiogenesis, Inflammation and Vessel Leakage May be Reduced in PlGF KO Mice



Role of PlGF in Angiogenesis



VIEW 1 & 2

Study Design

Multi-center, active controlled, double masked trial

Patients randomized 1:1:1:1

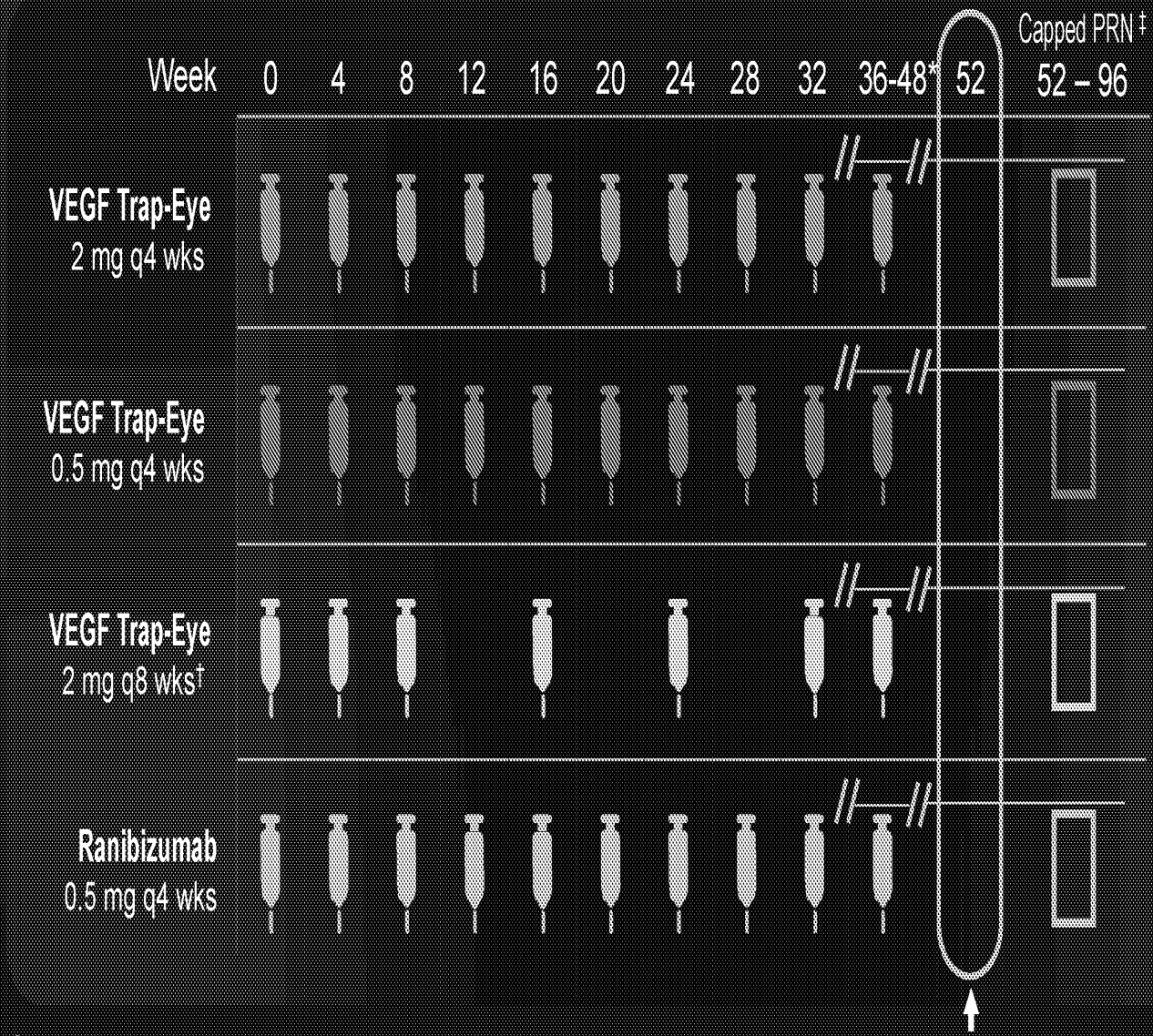
VIEW 1: N=1217

Ranibizumab	VEGF Trap-Eye		
RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8
			
0.5 mg q4 wks	2 mg q4 wks	0.5 mg q4 wks	2 mg q8 wks

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Biocon Exhibit 1012 - Page 5204

VIEW 1 & 2

Dosing Schedule



*Continued dosing at their respective intervals

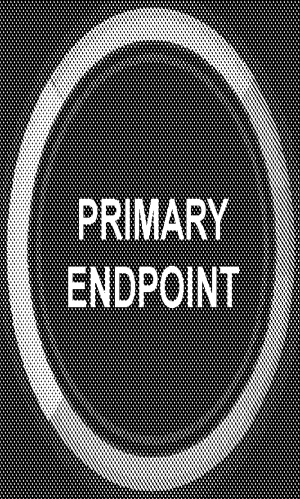
†After a loading dose period of 3-months

‡ Capped PRN: minimum injection frequency is q12 weeks

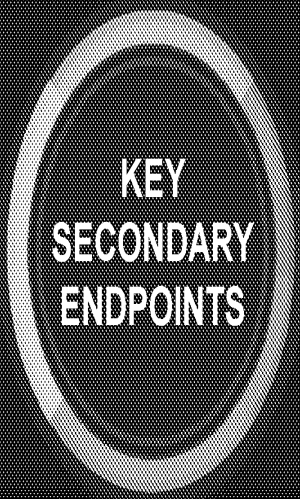
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Biocon Exhibit 1012 - Page 5205

VIEW 1 & 2

Study Endpoints



- Proportion of patients with prevention of moderate vision loss (< 15 letters lost on EDTRS eye chart)



- Mean change in visual acuity
- Proportion of patients who gain at least 15 letters of vision

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Biocon Exhibit 1012 - Page 5206

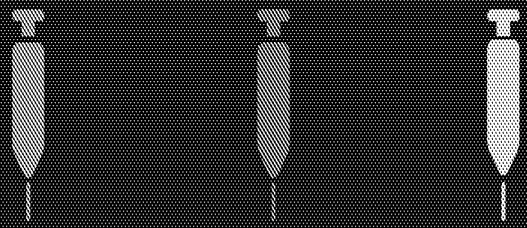
VIEW 1 & 2

Statistical Testing

PRIMARY ENDPOINT

Primary Endpoint tested using a non-inferiority paradigm with the non-inferiority margin set at 10%

Multiplicity controlled using a conditional sequence of confidence intervals as follows:



VTE 2q4	**VTE 0.5q4**	**VTE 2q8**
2 mg q4 wks	0.5 mg q4 wks	2 mg q8 wks

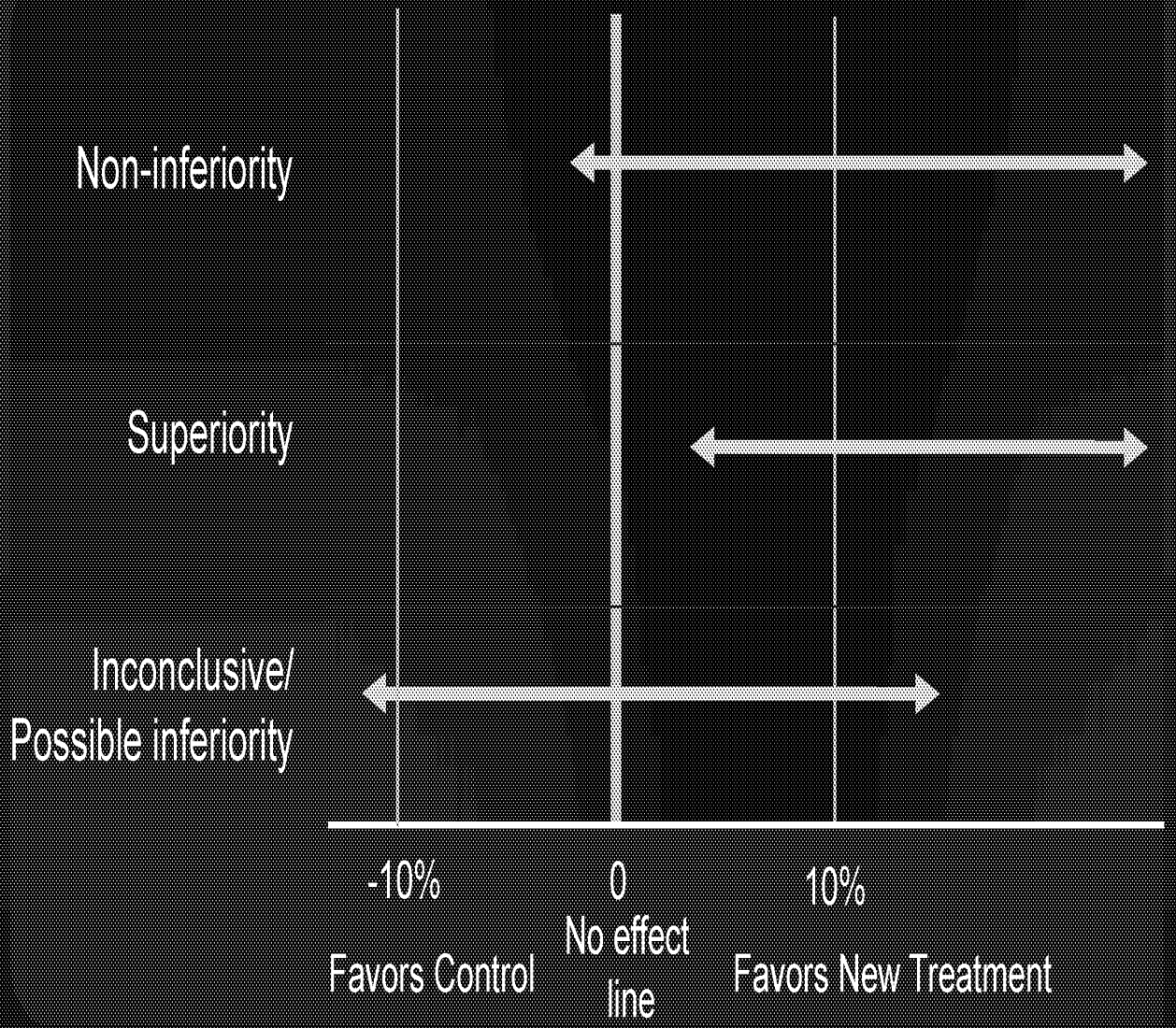
VTE considered non-inferior to RBZ if the confidence interval of the difference between RBZ and VTE lies entirely below 10%

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Statistical Rationale Behind the VIEW Program

- Objective: prove that VTE was non-inferior to RBZ
- Primary endpoint: the prevention of vision loss of greater than or equal to 15 letters on the ETDRS chart
- Non-inferiority was chosen for the following reasons:
  - Highly effective treatment available
- Data from previous Phase 3 Ranibizumab studies in AMD used to establish margin
- The non-inferiority margin was set at -10% from the “no difference line”

Illustrations of Superiority and Non-Inferiority



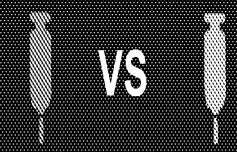
Samsung Bioepis Exhibit 1012 - Page 5209
Biocon Exhibit 1012 - Page 5209

VIEW 1 & 2

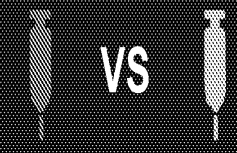
Statistical Testing

KEY SECONDARY ENDPOINTS

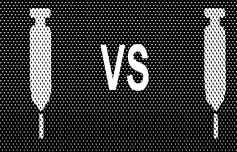
Key secondary endpoints tested for superiority using a conditional sequence of statistical hypothesis tests to control for multiplicity



VTE 2q4 RBZ 0.5q4



VTE 0.5q4 RBZ 0.5q4



VTE 2q8 RBZ 0.5q4

Mean change in visual acuity

Proportion of patients who gain at least 15 letters of vision

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Biocon Exhibit 1012 - Page 5210

VIEW 1
Patient Disposition

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
Randomized	306 (100%)	304 (100%)	304 (100%)	303 (100%)
Completed Week 52	284 (92.8%)	293 (96.4%)	277 (91.1%)	276 (91.1%)
Discontinuation Before Wk 52	22 (7.2%)	11 (3.6%)	27 (8.9%)	27 (8.9%)
Withdrawal Of Consent	10 (3.3%)	5 (1.6%)	7 (2.3%)	8 (2.6%)
Protocol Deviation	3 (1.0%)	0	3 (1.0%)	1 (0.3%)
Adverse Event	4 (1.3%)	3 (1.0%)	5 (1.6%)	4 (1.3%)
Discontinuation due to Death*	3 (1.0%)	1 (0.3%)	2 (0.7%)	7 (2.3%)
Lost To Follow-Up	1 (0.3%)	2 (0.7%)	4 (1.3%)	4 (1.3%)
Lack of efficacy	0	0	2 (0.7%)	2 (0.7%)
Other†	1 (0.3%)	0	4 (1.3%)	1 (0.3%)

*Total number of deaths: Rq4: 5 (1.6%), 2q4: 2 (0.7%), 0.5q4: 2 (0.7%), 2q8: 8 (2.6%)
†Investigator decision, no leakage, non compliance, health issues, patient decision

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Biocon Exhibit 1012 - Page 5211

VIEW 1

Baseline Demographics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	304	304	301	301
Mean Age (years)	78.2 ± 7.6	77.7 ± 7.9	78.4 ± 8.0	77.9 ± 8.4
Gender				
Women (%)	56.6%	63.8%	55.5%	59.1%
Men (%)	43.4%	36.2%	44.5%	40.9%
Race (%)				
White	97.4%	97.0%	96.7%	95.3%
Other	1.3%	1.3%	2.4%	2.2%
Not Reported/Multi Racial	1.3%	1.6%	1%	2.3%

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Biocon Exhibit 1012 - Page 5212

VIEW 1

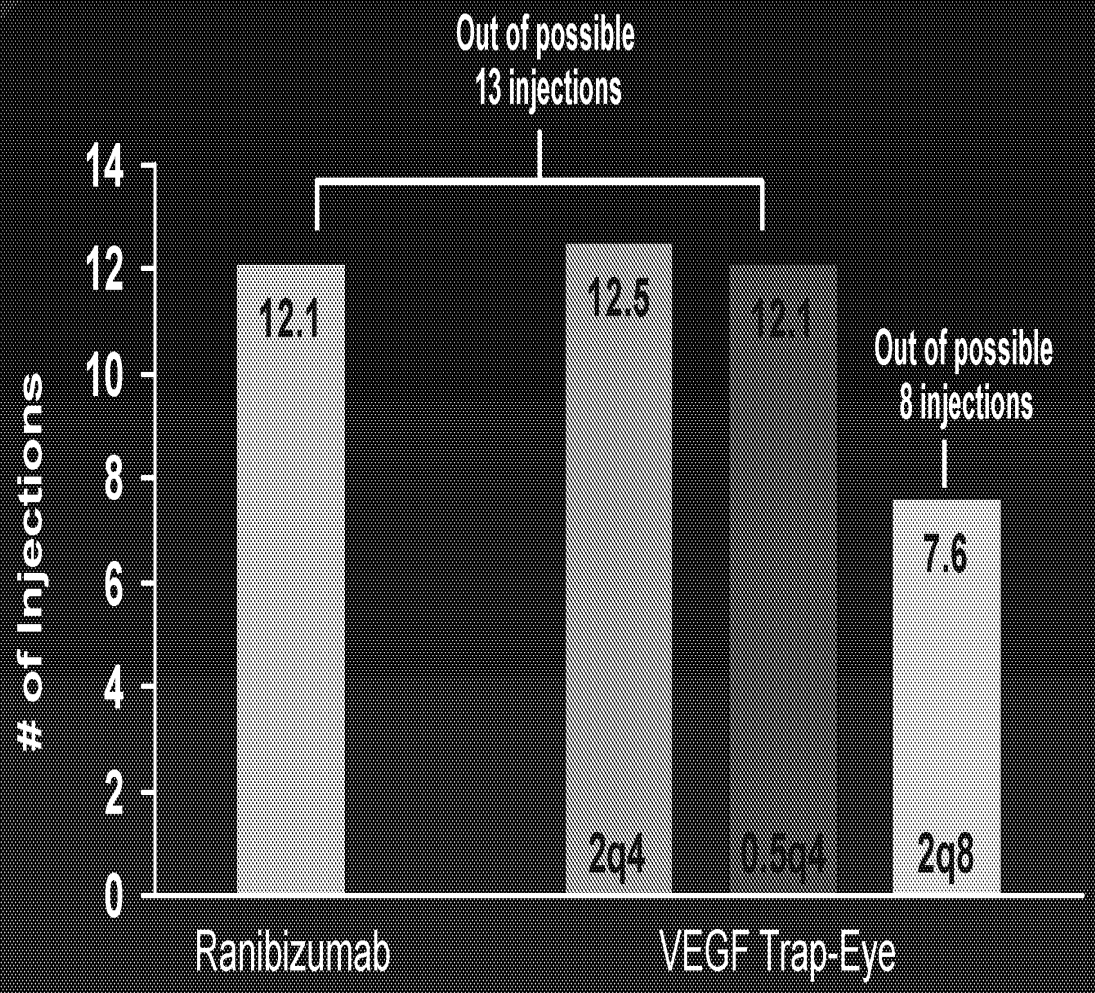
Baseline Disease Characteristics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	304	304	301	301
ETDRS BCVA (letter score±SD) Snellen Equivalent	54 ± 13 20/80	55 ± 13 20/80	56 ± 13 20/80	56 ± 13 20/80
Lesion Type: (%)				
Predominantly Classic	27.0%	28.6%	26.9%	23.6%
Minimally Classic	33.2%	34.5%	32.2%	36.5%
Occult no classic	37.8%	36.2%	40.2%	39.2%
Lesion Size (mm^2, mean ± SD)	7.0 ± 5.5	7.0 ± 5.4	7.0 ± 4.7	7.0 ± 5.2
Total Retina/LesionThickness (µm ± SD)	493 ± 183	476 ± 163	482 ± 182	496 ± 181

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VIEW 1

Number of Active Injections Through 1 Year



*Out of possible 13 for Q4 groups and 8 for Q8 group

Full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;

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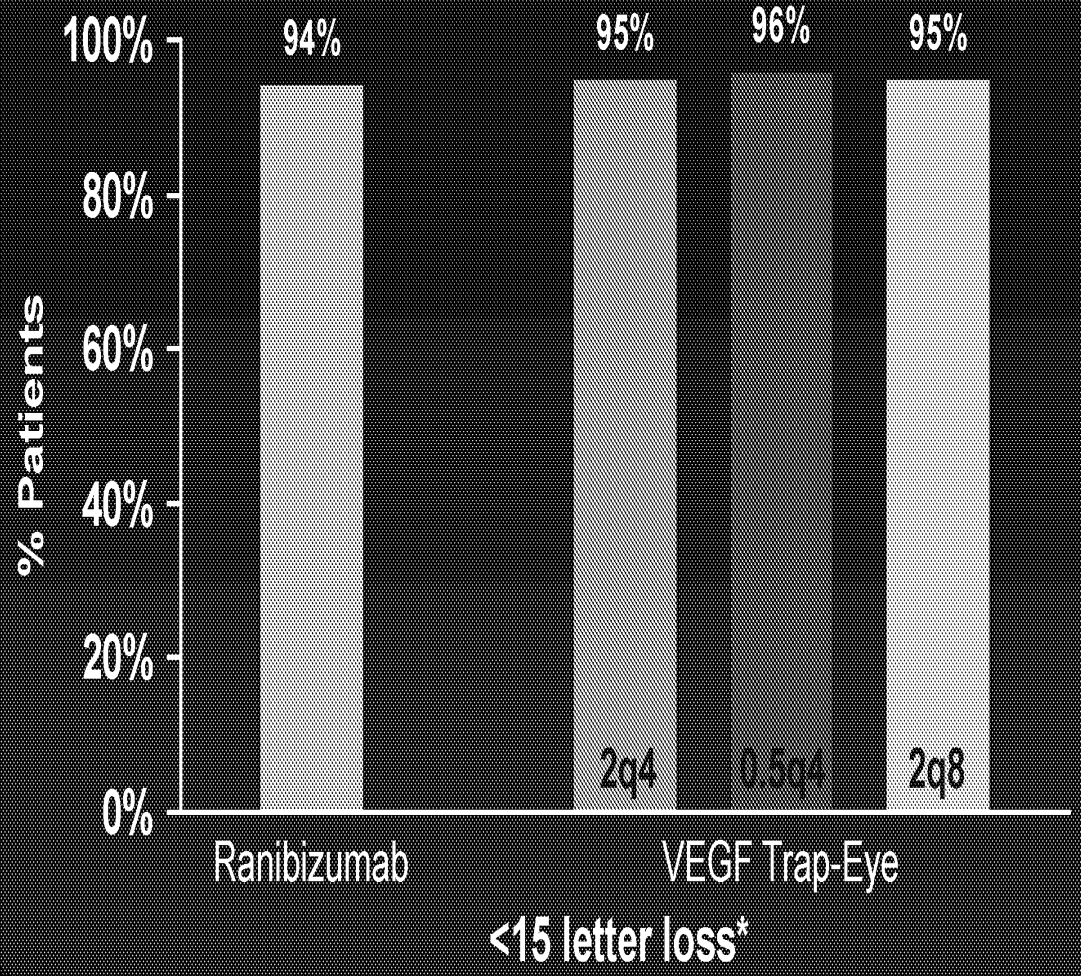


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VIEW 1 Study

Primary Endpoint: Maintenance of Vision at 1 Year

All doses of VEGF Trap-Eye were non-inferior to ranibizumab

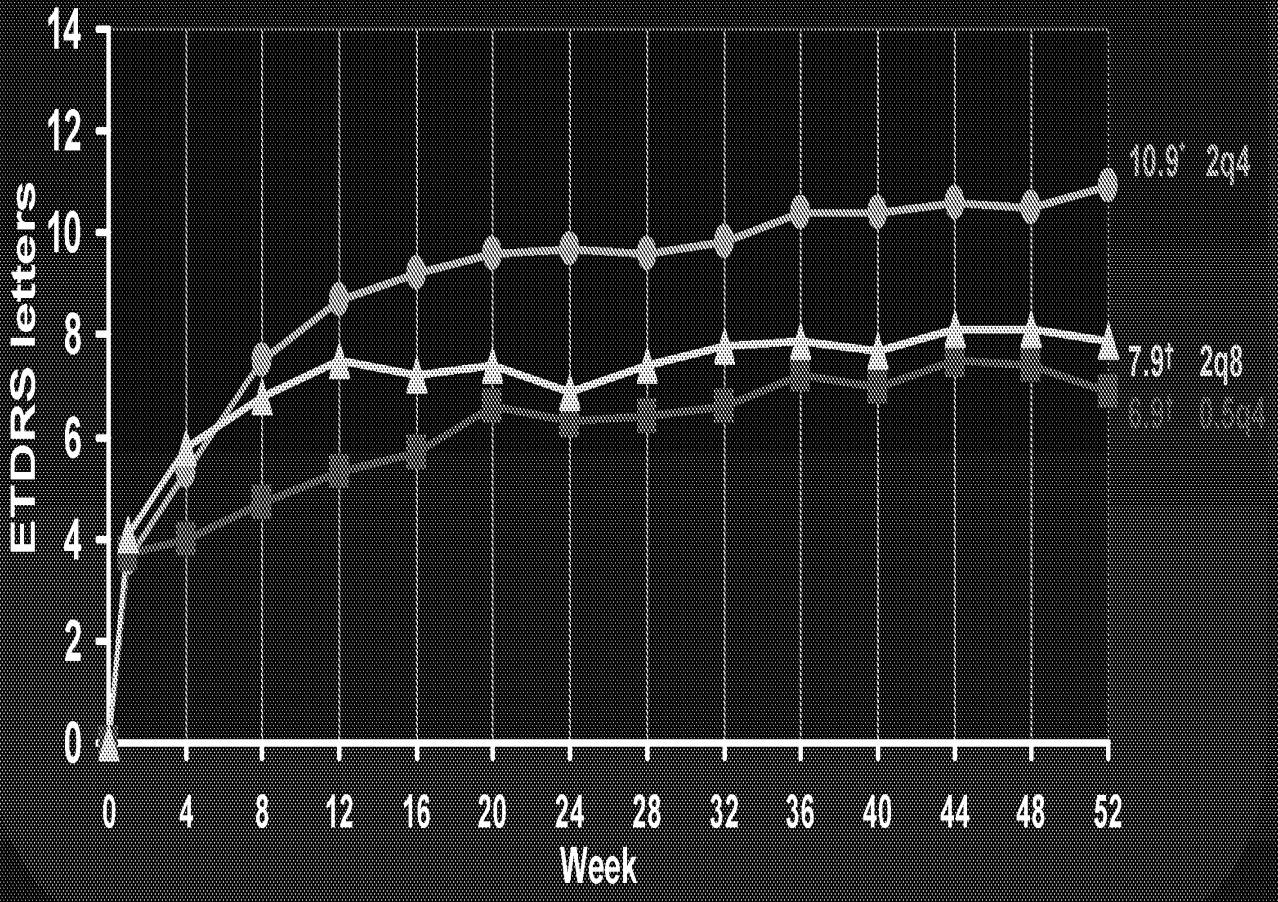


*Compared to baseline; LOCF; per protocol set: Rq4 n=269; 2q4 n=285; 0.5q4 n=270; 2q8 n=265

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VIEW 1

Mean Change in Visual Acuity to 1 year Compared to Baseline



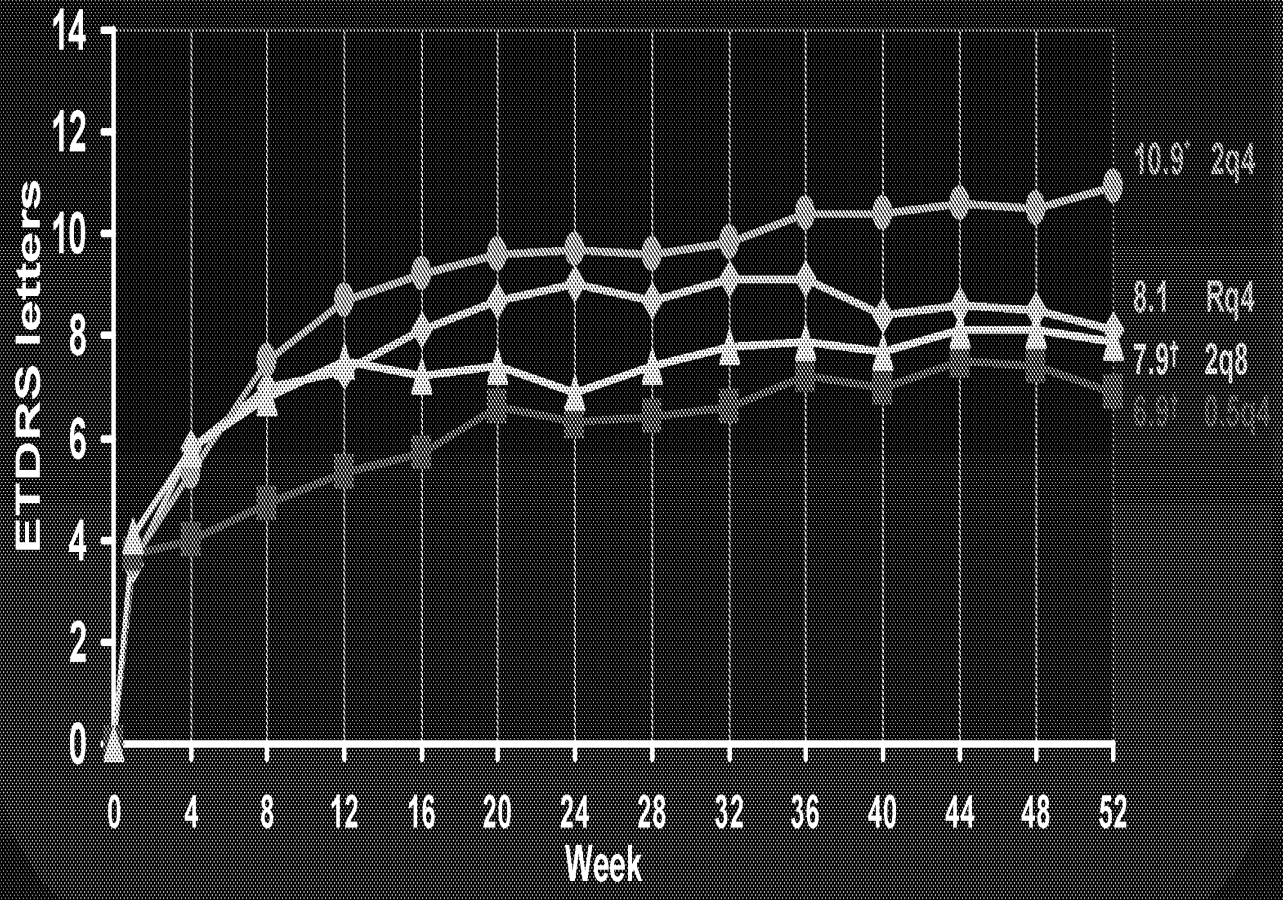
*P = 0.0054
†P = NS
vs. Rq4

LOCF; full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;

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VIEW 1

Mean Change in Visual Acuity to 1 year Compared to Baseline



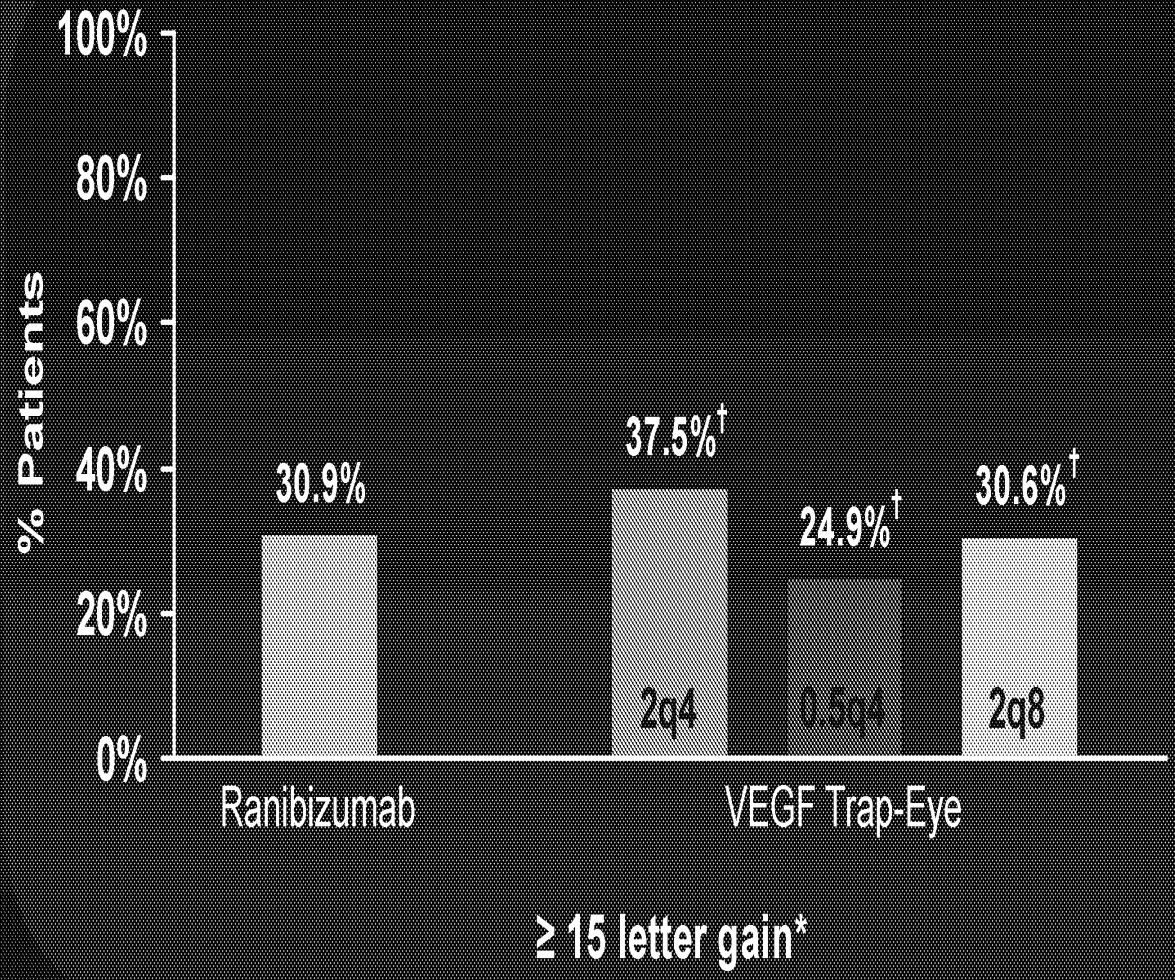
*P = 0.0054
†P = NS
vs. Rq4

LOCF; full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;

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VIEW 1

Proportion of Patients Who Gained ≥ 15 letters



≥ 15 letter gain*

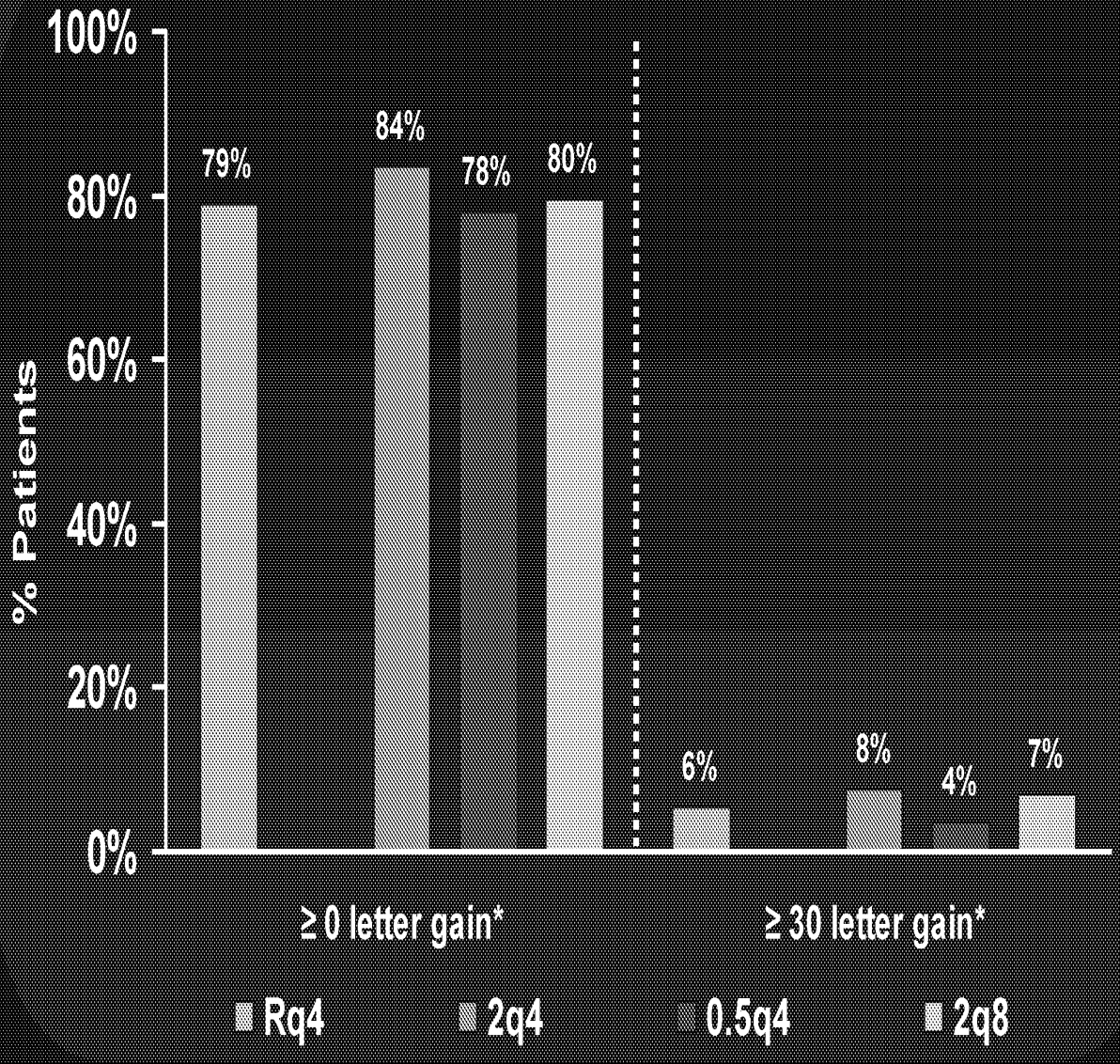
†*P* = NS vs. Rq4

*Compared to baseline; LOCF; full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;

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VIEW 1

Vision Changes at 1Year*

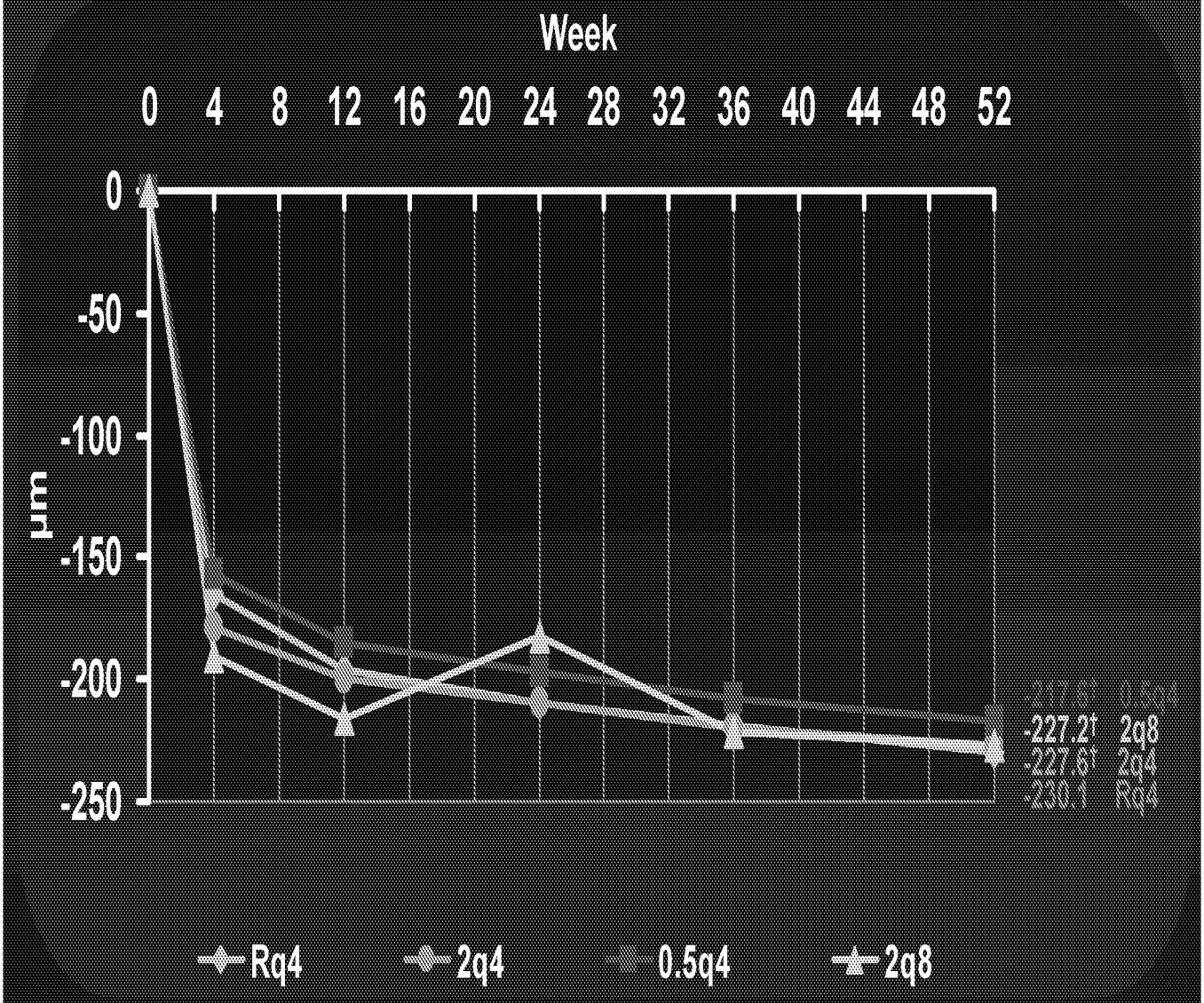


*Compared to baseline; Full analysis set; Rq4 n=304; 2q4 n=304; 0.5q4 n=301; 2q8 n=301;

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Biocon Exhibit 1012 - Page 5220

VIEW 1

Mean Change in Total Retina/Lesion Thickness



OCTs mandatory at BL, wks 4, 12, 24, 36, 52; LOCF;

Full analysis set; Rq4 n=302; 2q4 n=303; 0.5q4 n=299; 2q8 n=301

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Safety

VIEW 1

% Patients with Study Eye Ocular Serious Adverse Events

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
n (safety analysis set)	304	304	304	303	911
# subjects with at least 1 SAE	9 (3.0%)	7 (2.3%)	5 (1.7%)	3 (1.0%)	15 (1.6%)
Endophthalmitis	3 (1.0%)	3 (1.0%)	0	0	3 (0.3%)
Culture positive	1	2			
Culture negative	1	1			
Unknown	1				
Visual acuity reduced	2 (0.7%)	1 (0.3%)	2 (0.7%)	0	3 (0.3%)
Retinal hemorrhage	2 (0.7%)	0	0	2 (0.7%)	2 (0.2%)
Angle closure glaucoma	0	1 (0.3%)	0	0	1 (0.1%)
Cataract	0	0	1 (0.3%)	0	1 (0.1%)
Keratitis	0	1 (0.3%)	0	0	1 (0.1%)
Macular hole	0	0	1 (0.3%)	0	1 (0.1%)
Retinal degeneration	0	1 (0.3%)	0	0	1 (0.1%)
Retinal detachment	0	0	1 (0.3%)	0	1 (0.1%)
Retinal edema	0	0	1 (0.3%)	0	1 (0.1%)
RPE tear	0	0	0	1 (0.3%)	1 (0.1%)
Retinal tear	1 (0.3%)	0	0	0	0
Incorrect dose administered	1 (0.3%)	0	0	0	0
IOP increased	1 (0.3%)	0	0	0	0

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VIEW 1
Deaths

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	304	304	304	303	911
All Deaths*	5 (1.6%)	2 (0.7%)	2 (0.7%)	8 (2.6%)	12 (1.3%)
Myocardial Infarction	1	0	1	2	3
Stroke	0	0	0	1	1
Cerebral Hemorrhage	0	0	1	0	1
Ruptured AAA	0	0	0	1	1
Congestive Heart Failure	1	0	0	2	2
Respiratory (Pneumonia and COPD)	1	1	0	1	2
Cancer Related	2	1	0	1	2

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VIEW 1

% Patients with APTC Events through 1 Year

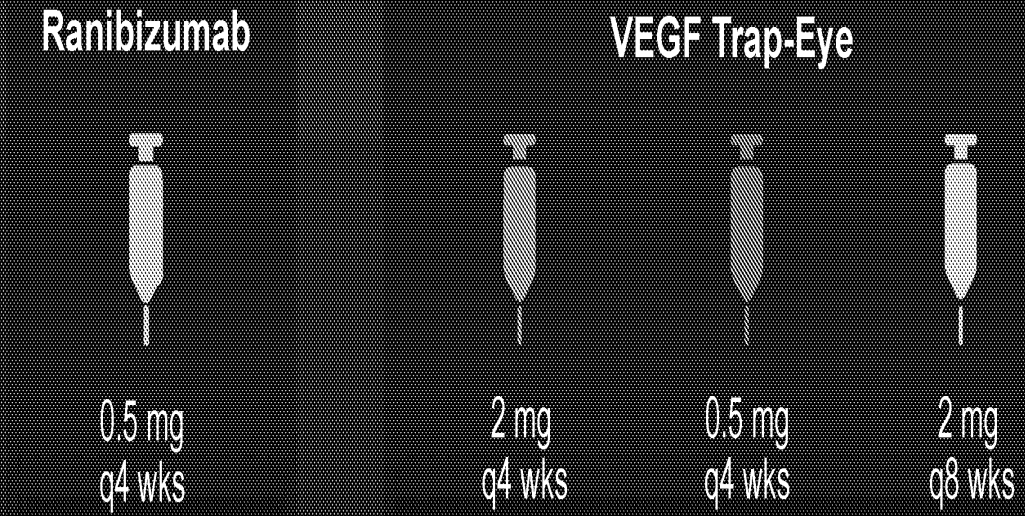
	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	304	304	304	303	911
Any APTC event	5 (1.6%)	2 (0.7%)	7 (2.3%)	6 (2.0%)	15 (1.6%)
Vascular Deaths	1 (0.3%)	0	1 (0.3%)	4 (1.3%)	5 (0.5%)
Non Fatal MI	4 (1.3%)	1 (0.3%)	4 (1.3%)	1 (0.3%)	6 (0.7%)
Non Fatal Stroke[a]	0	1 (0.3%)	2 (0.7%)	1 (0.3%)	4 (0.4%)

[a]All non fatal strokes were ischemic in nature

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VIEW 1
Conclusions

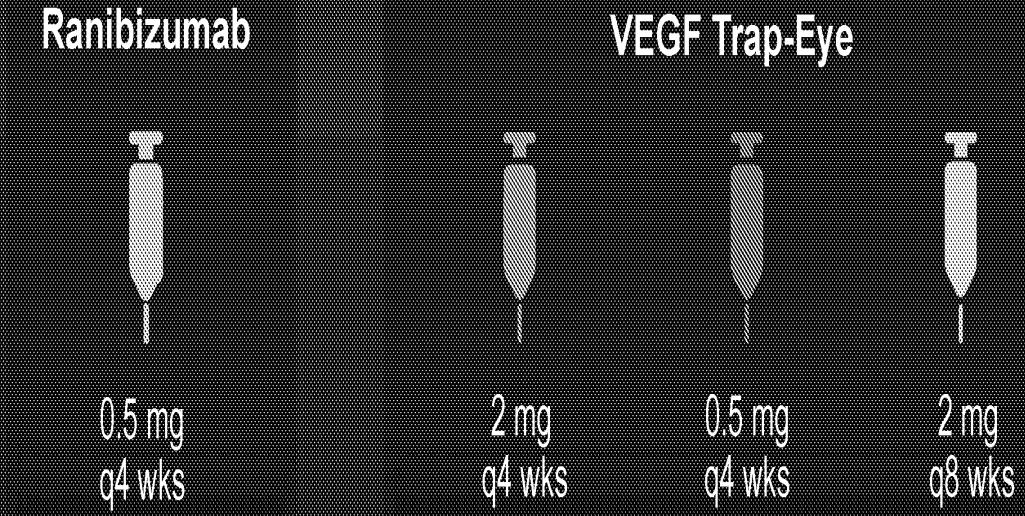
- VEGF Trap-Eye (0.5 mg or 2 mg monthly, and 2 mg every other month) was comparable to 0.5 mg monthly Ranibizumab



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VIEW 1
Conclusions

- VEGF Trap-Eye was well-tolerated across all doses and dose regimens
  - Similar ocular and systemic safety profile as ranibizumab



Samsung Bioepis Exhibit 1012 - Page 5227
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Conclusions

VEGF Trap-Eye offers the potential of outstanding visual and anatomic outcomes of anti-VEGF therapy that we have come to expect, with a significant decrease in the treatment burden that patients, their families, and clinicians have come to endure.

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Biocon Exhibit 1012 - Page 5228

Vascular Endothelial Growth Factor (VEGF) Trap-Eye 1-Year Results:

Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD)

VIEW 2

Ursula Schmidt-Erfurth
Department of Ophthalmology
Medical University of Vienna
Austria

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Financial Disclosures

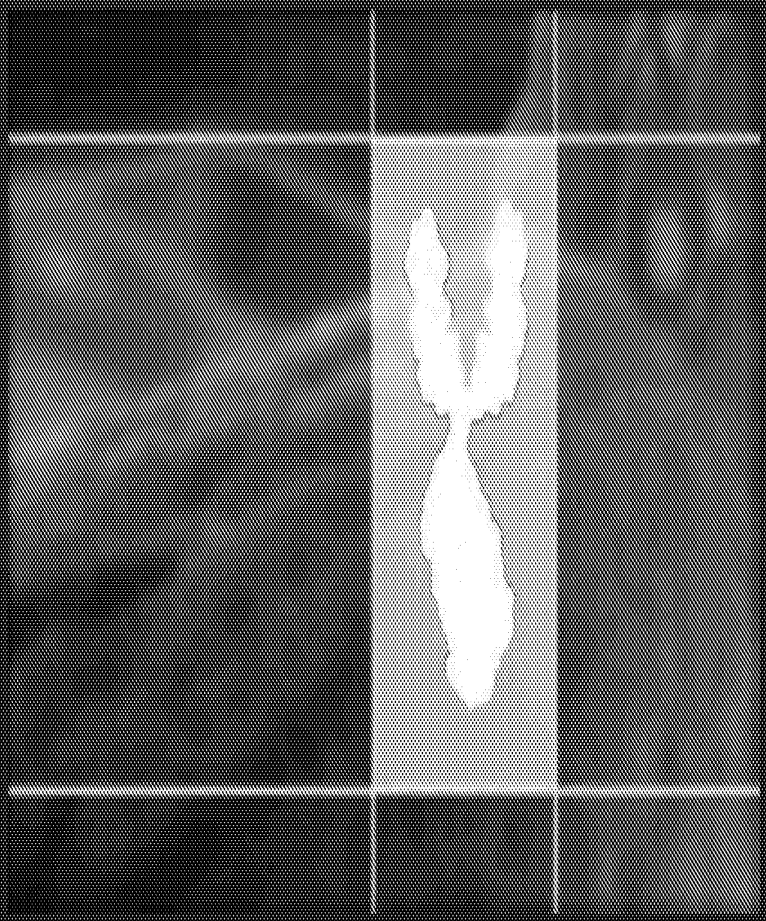
- Consultant for Alcon, Allergan, Bayer, Carl Zeiss Meditec, Genentech, Novartis, Pfizer
- Performing contract research for Alcon, Bayer and Novartis
- Under the guidelines of the Medical University of Vienna

VEGF Trap Concept

- VEGF trap (aflibercept) is a designed fusion protein:

  A chimeric soluble decoy receptor moiety composed of the extracellular domains of VEGF receptor 1 and 2 fused to the Fc part of human IgG1

VEGF Trap Concept

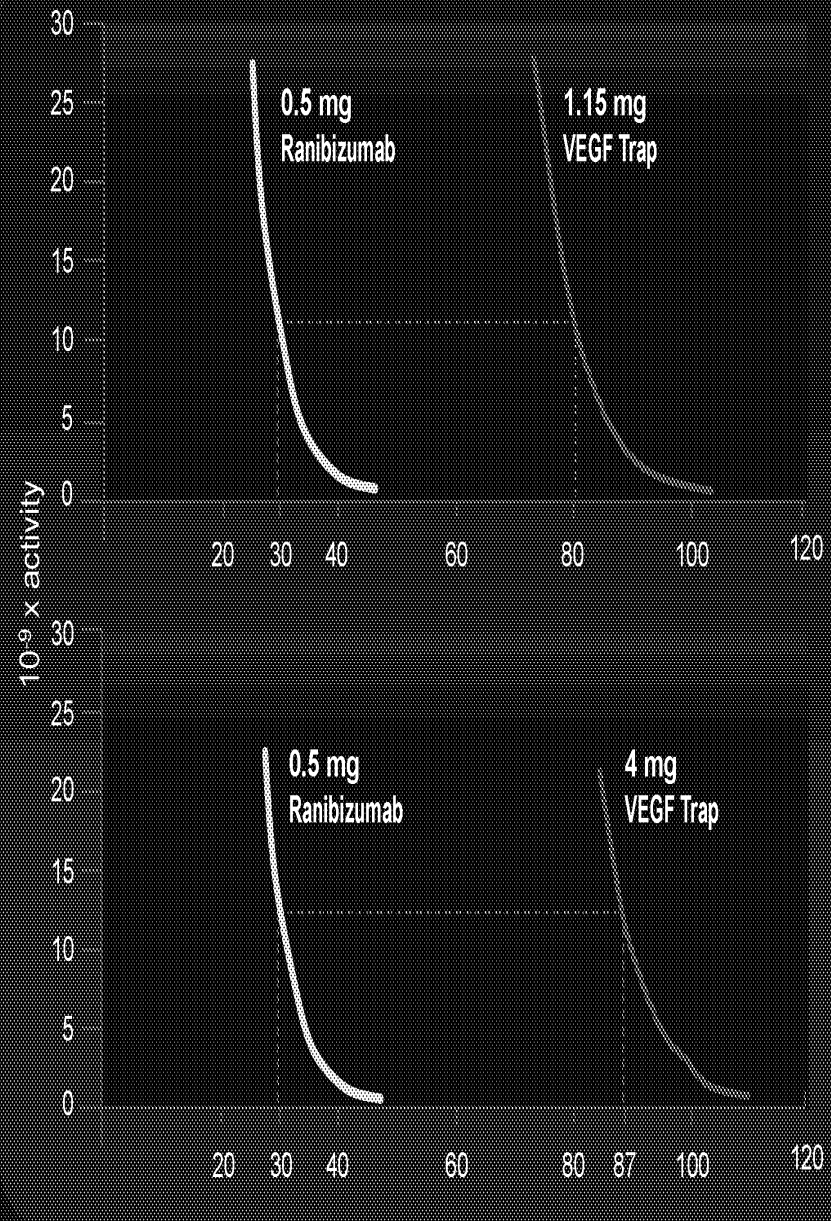


VEGF Trap Concept

- Role of the Fc portion is to prolong the half-life due to the interaction of Fc with the neonatal FcRn receptor

- The characteristics of the fusion protein are:
  - binding to all VEGF isoforms: VEGF A, B, C
  - binding of placental growth factor (PlGF)
  - 10 fold higher affinity than bevacizumab
  - no cross-reaction with any tyrosine kinase receptor
  - induction of rapid endothelial cell death

Modeling of Prolonged Biological Activity of Intravitreal VEGF Trap-Eye



- Biological activity of equimolar VEGF Trap 1.15mg at 79 days comparable to ranibizumab 0.5mg at 30 days
- Biological activity of VEGF Trap 4mg at 87 days is comparable to that of ranibizumab 0.5mg at 30 days

Based on this model, 2 mg VEGF Trap-Eye at 83 days would provide similar biological activity to ranibizumab 0.5 mg at 30 days

MW Stewart, PJ Rosenfeld Br J *Ophthalmol* 2008;92:667–668.

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Biocon Exhibit 1012 - Page 5234

Therapeutic fusion proteins on the market

Chemical /Common Name	Brand Name	Target	Structure	Licensed Indication, Target Diseases	Mode of action	Manufacturer and/or Distributor
Abatacept	Orencia	B7-1 (CD80), B7-2 (CD86) costimulatory molecules on APC	CTLA4 (cytotoxic T-lymphocyte antigen-4)-Human IgG1 Fusion protein	Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis	binding to the B7 protein on APCs and preventing them from delivering the costimulatory signal to T cells (CD28), thus preventing the full activation of T cells	Bristol Myers Squibb
Alefacept	Amvive (not EMEA approved)	CD2	LFA-3-IgG1 Fc fusion protein	moderate to severe, chronic plaque psoriasis	Inhibits lymphocyte activation by blocking co-stimulatory molecule interaction LFA-3/CD2, and induces apoptosis in memory-effector T cells	Astellas Pharma Biogen IDEC
Denileukin diftitox	ONTAK	IL-2 Receptor	recombinant fusion protein expressing amino acid residues of diphtheria toxin fragment A & B, followed by the sequence for IL-2	recurrent CD25 positive, cutaneous T-cell lymphoma	The protein binds to IL-2 receptors on T-cells. The diphtheria toxin is then internalized, killing the T-cell.	Eisai
Etanercept	Enbrel	TNFα and TNFβ	TNFR2-IgG1 Fc fusion protein	RA, Juvenile Idiopathic Arthritis psoriatic arthritis, ankylosing spondylitis, plaque psoriasis	TNF inhibitor	Amgen Wyeth
Rilonacept	Arcalyst (Orphan Drug)	IL-1	Extracellular domain of IL1-R and IgG1 Fc	Cryopirin-associated periodic syndromes (CAPS)	Binds and neutralize IL-1	Regeneron

Introduction

- Two identical trials including a total number of 2457 patients with active, treatment-naïve neovascular AMD were performed
- Primary study outcome was defined as non-inferiority between VEGF Trap-Eye (VTE) arms and standard therapy with monthly ranibizumab injections
- Intravitreal VEGF Trap-Eye regimens included 0.5mg and 2mg monthly and 2mg every two months following a loading regimen
- Functional (BCVA) and anatomical (OCT) responses were documented

VIEW 1 & 2

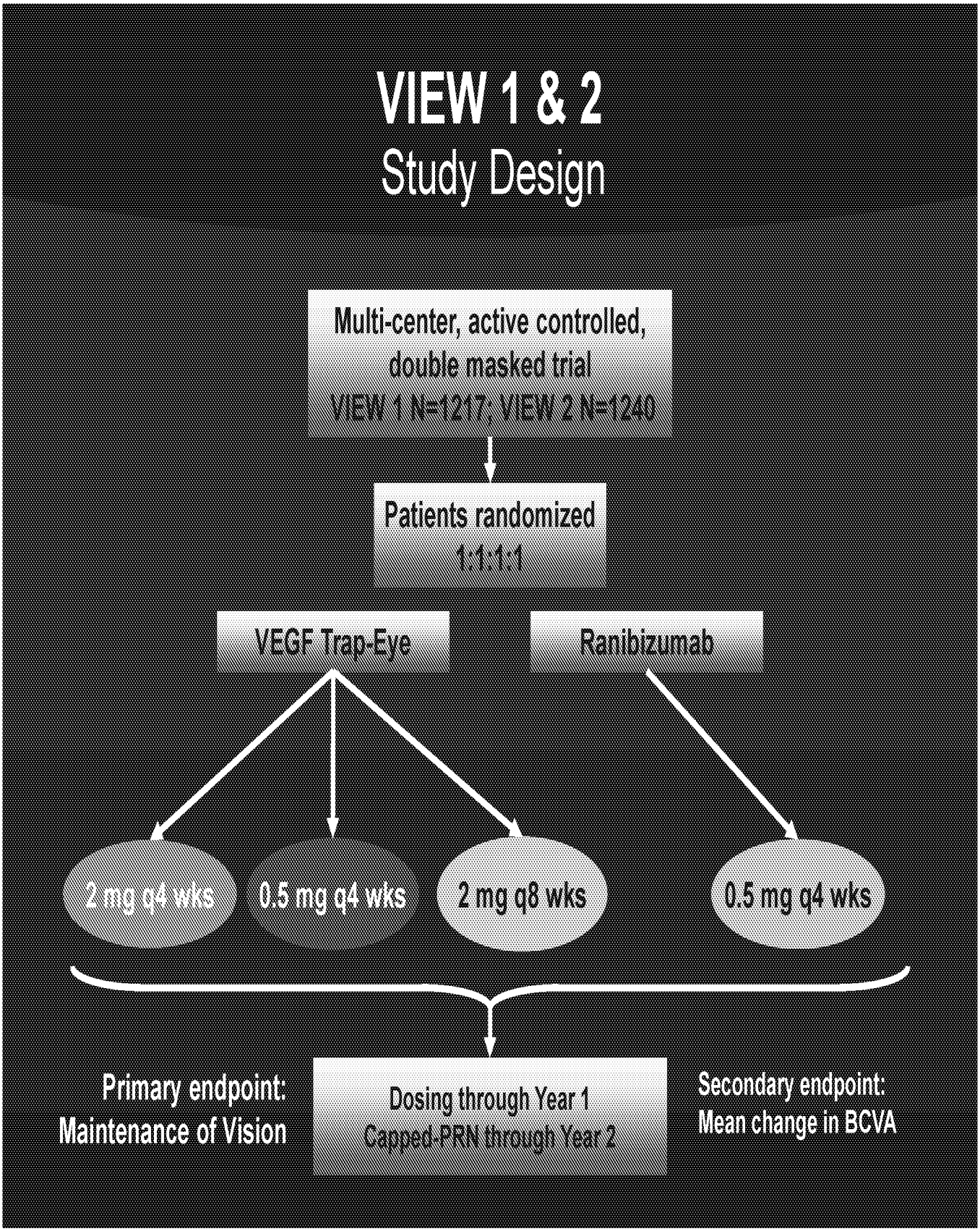
Study Design

Multi-center, active controlled, double masked trial

Ranibizumab	VEGF Trap-Eye		
RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8
			
0.5 mg q4 wks	2 mg q4 wks	0.5 mg q4 wks	2 mg q8 wks

9

VIEW 1 & 2
Study Design



VIEW 2
Patient Disposition

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
Randomized	303 (100%)	313 (100%)	311 (100%)	313 (100%)
Completed Week 52	276 (91.1%)	281 (89.8%)	274 (88.1%)	284 (90.7%)
Discontinuation Before Wk 52	27 (8.9%)	32 (10.2%)	37 (11.9%)	29 (9.3%)
Adverse event	2 (0.7%)	6 (1.9%)	8 (2.6%)	9 (2.9%)
Discontinuation due to Death*	1 (0.3%)	3 (1.0%)	2 (0.6%)	1 (0.3%)
Lost to Follow-up	4 (1.3%)	1 (0.3%)	2 (0.6%)	2 (0.6%)
Other	7 (2.3%)	6 (1.9%)	10 (3.2%)	5 (1.6%)
Protocol Violation	2 (0.7%)	1 (0.3%)	1 (0.3%)	0
Treatment failure	0	0	1 (0.3%)	1 (0.3%)
Withdrawal by subject	11 (3.6%)	15 (4.8%)	13 (4.2%)	11 (3.5%)

*Total number of deaths: Rq4: 2 (0.7%), 2q4: 3 (1.0%), 0.5q4: 2 (0.7%), 2q8: 2 (0.7%)

VIEW 2

Baseline Demographics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	291	309	296	306
Age (years) ± SD	73.0 ± 9.0	74.1 ± 8.5	74.7 ± 8.6	73.8 ± 8.6
Gender				
Women (%)	58.1%	57.0%	49.7%	57.2%
Men (%)	41.9%	43.0%	50.3%	42.8%
Race (%)				
White	73.2%	73.1%	74.0%	70.9%
Asian	20.6%	21.7%	20.6%	22.5%
Black	0.3%	0	0.3%	0.7%
Not Reported	5.8%	5.2%	5.1%	5.9%

VIEW 1 & 2

Baseline Demographics

	VIEW 1 All Groups	VIEW 2 All Groups
n (full analysis set)	1210	1202
Age (years)	78.1	73.9
Women (%)	58.8%	55.5%
Race (%)		
Caucasian	96.6%	72.8%
Asian	1.0%	21.4%
Other/Not Reported	2.4%	5.8%

VIEW 2

Baseline Disease Characteristics

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks
n (full analysis set)	291	309	296	306
ETDRS BCVA (letter score ± SD) Snellen Equivalent	54 ± 14 20/80	53 ± 14 20/100	52 ± 14 20/100	52 ± 14 20/100
Lesion Type: (%)				
Predominantly Classic	24.1%	23.3%	27.0%	28.8%
Minimally Classic	35.7%	36.2%	34.8%	34.6%
Occult no classic	39.9%	39.8%	38.2%	35.9%
Tot. Lesion Size (mm2, mean ± SD)	8.0 ± 5.7	8.7 ± 6.1	8.2 ± 5.5	8.2 ± 5.9
Central Retinal Thickness (µm ± SD)	326 ± 111	335 ± 120	327 ± 116	343 ± 124

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Biocon Exhibit 1012 - Page 5242

VIEW 1 & 2

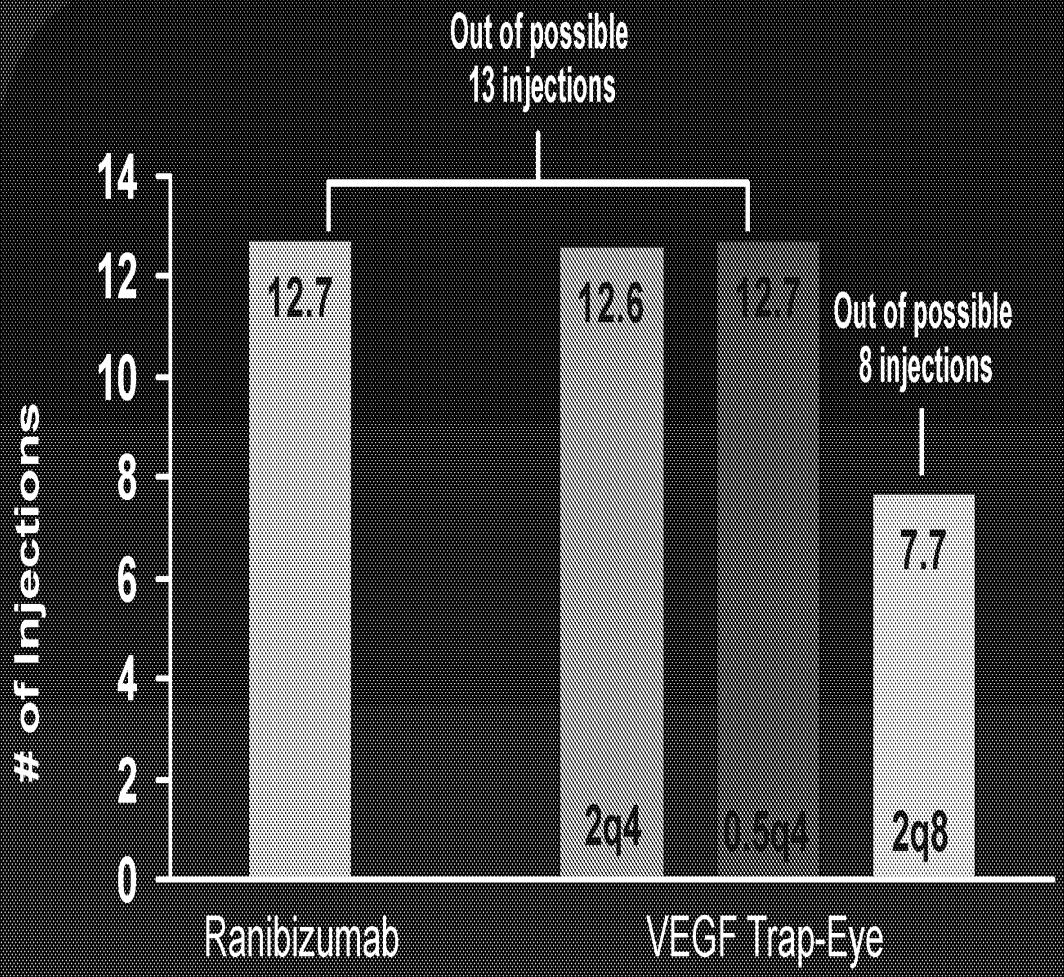
Baseline Disease Characteristics

	VIEW 1 All Groups
n (full analysis set)	1210
ETDRS BCVA (letter score ± SD)	55 ± 13
Lesion Type: (%)	
Predominantly Classic	26.5%
Minimally Classic	34.1%
Occult no classic	38.3%
Lesion Size (mm^2, mean ± SD)	7.0 ± 5.2
Total Retina/ Lesion Thickness (µm ± SD)	487 ± 177

	VIEW 2 All Groups
n (full analysis set)	1202
ETDRS BCVA (letter score ± SD)	52 ± 14
Lesion Type: (%)	
Predominantly Classic	25.8%
Minimally Classic	35.4%
Occult no classic	38.4%
Lesion Size (mm^2, mean ± SD)	8.3 ± 5.8
Central Retinal Thickness (µm ± SD)	333 ± 118

VIEW 2

Number of Active Injections Through 1 Year



Mean Number of Injections*

*Out of possible 13 for Q4 groups and 8 for Q8 group

Full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306

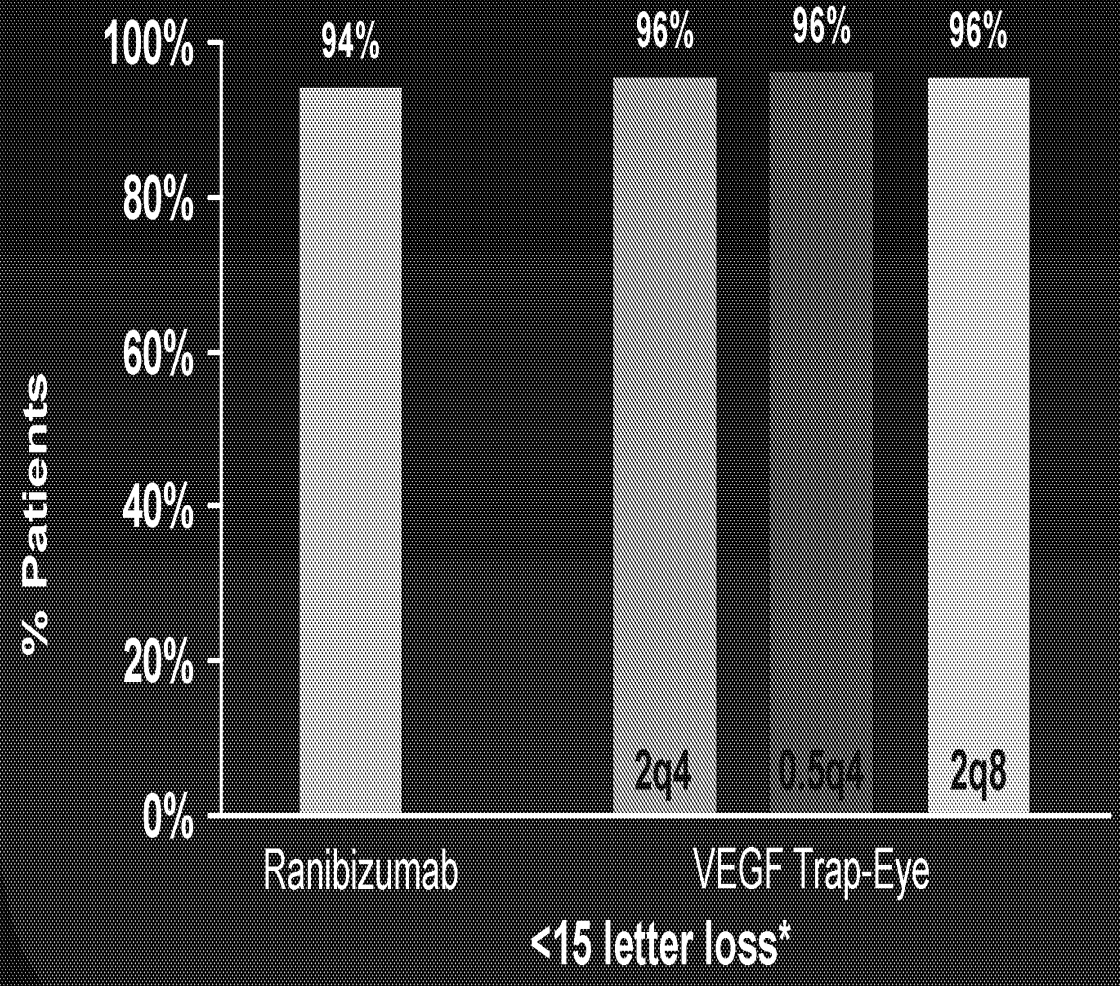


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VIEW 2

Primary Endpoint: Prevention of Moderate Vision Loss

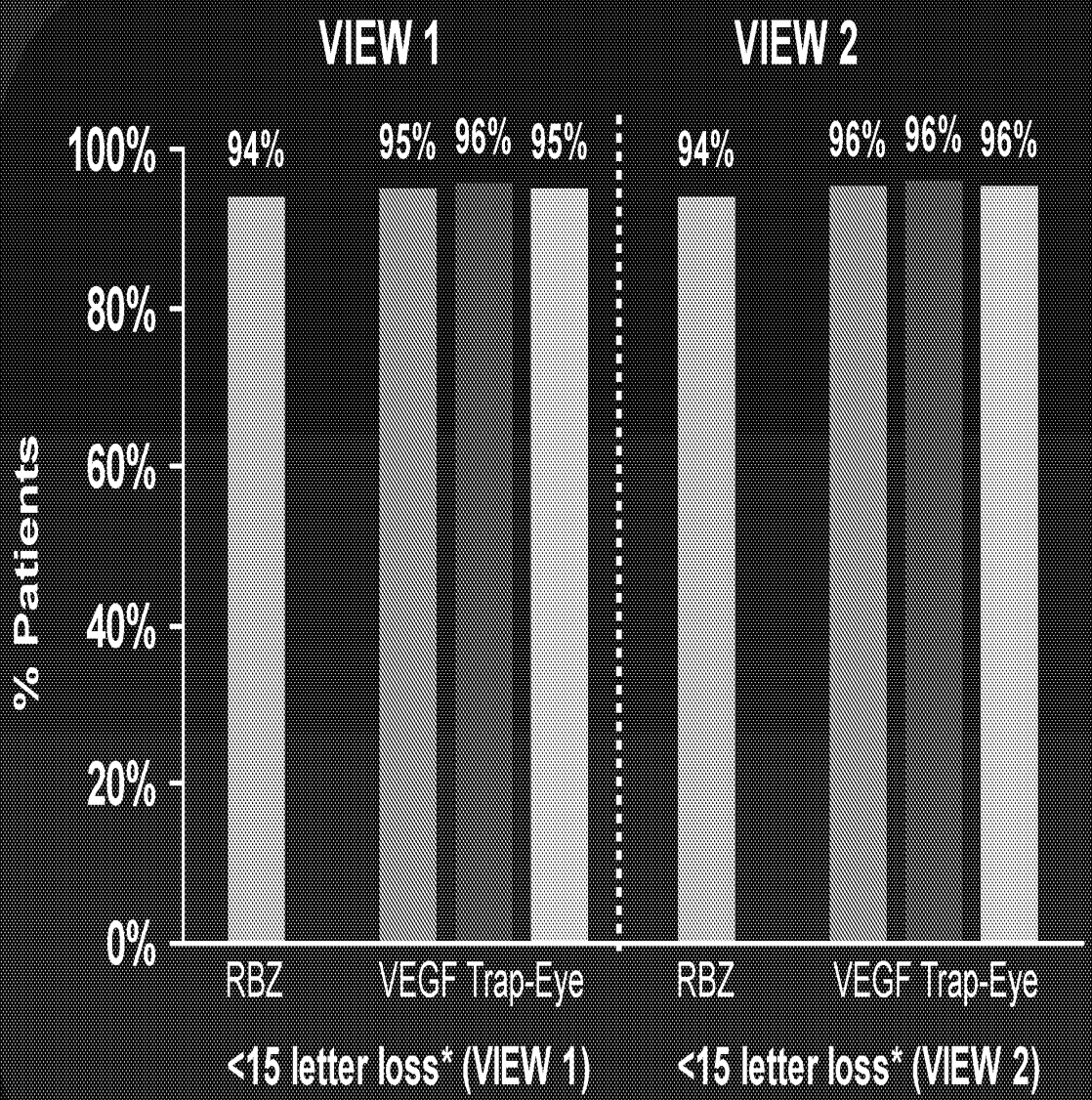
All doses of VEGF Trap-Eye were non-inferior to ranibizumab



*Compared to baseline; LOCF; per protocol set: Rq4 n=269; 2q4 n=274; 0.5q4 n=268; 2q8 n=270

VIEW 1 & 2

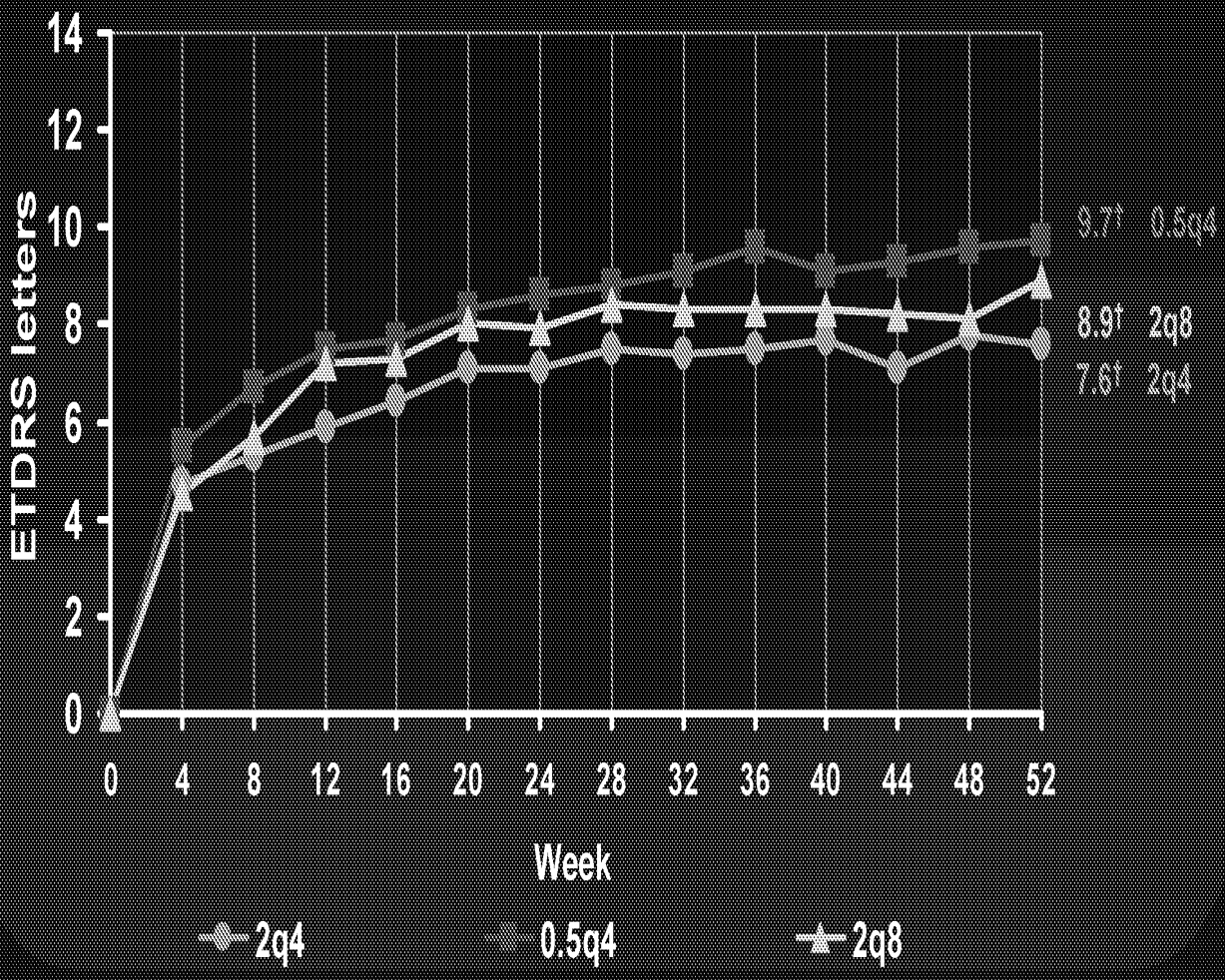
Primary Endpoint: Prevention of Moderate Vision Loss



*Compared to baseline; LOCF; VIEW 1 pps: Rq4 n=269; 2q4 n=285; 0.5q4 n=270; 2q8 n=265
VIEW 2 pps: Rq4 n=269; 2q4 n=274; 0.5q4 n=268; 2q8 n=270

VIEW 2

Mean Change in Visual Acuity to 1 year Compared to Baseline

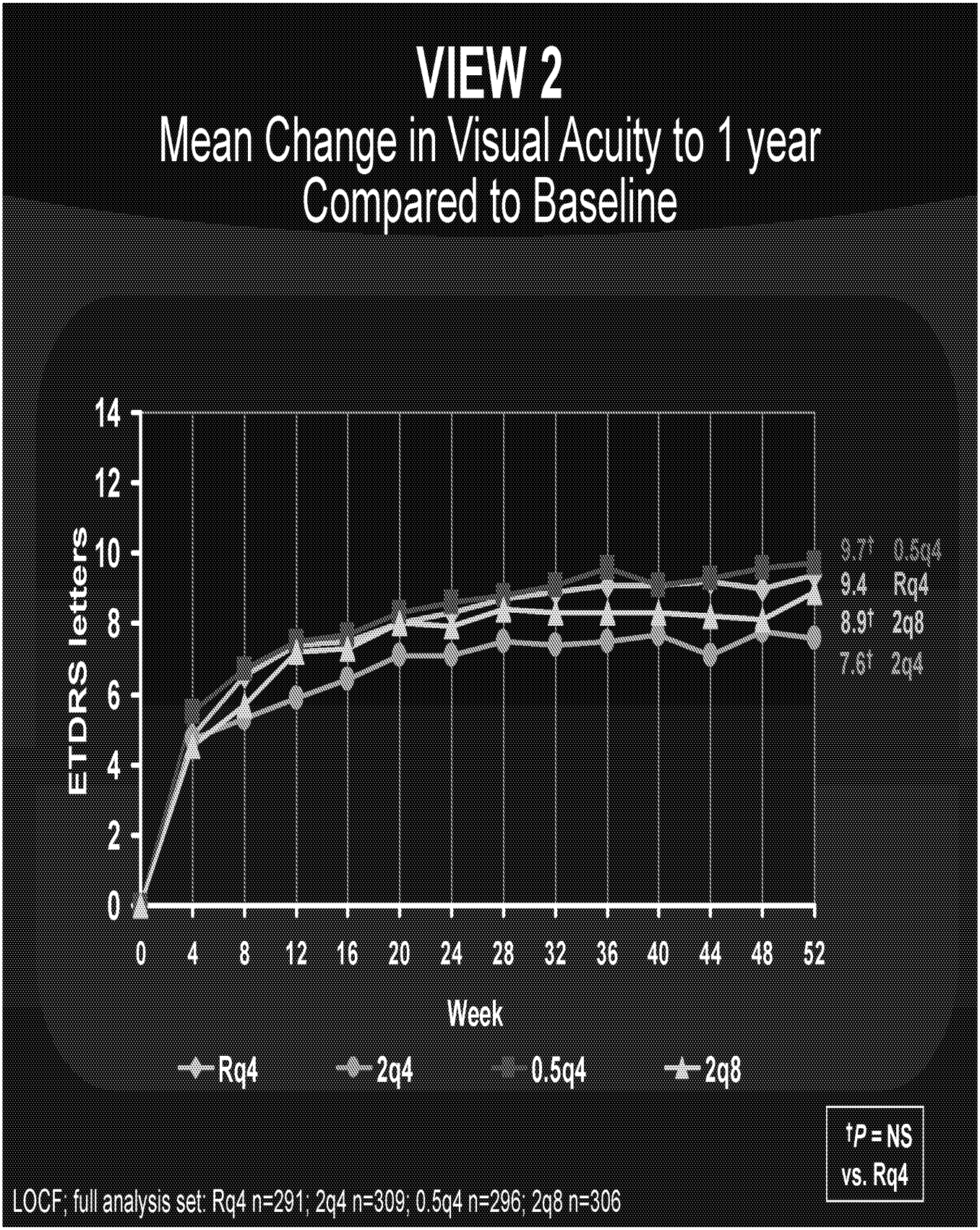


†*P* = NS vs. Rq4

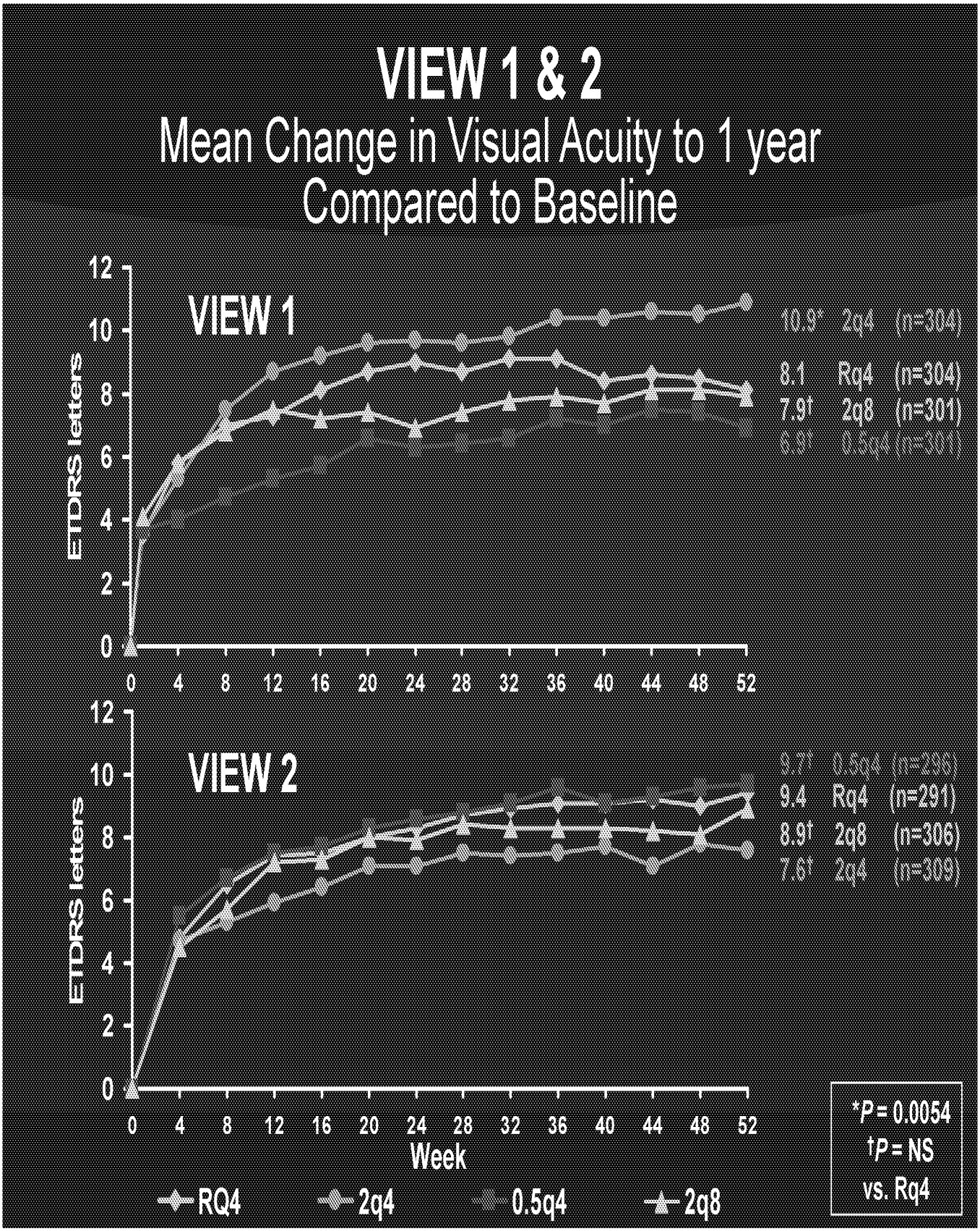
LOCF; full analysis set: Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306

VIEW 2

Mean Change in Visual Acuity to 1 year Compared to Baseline

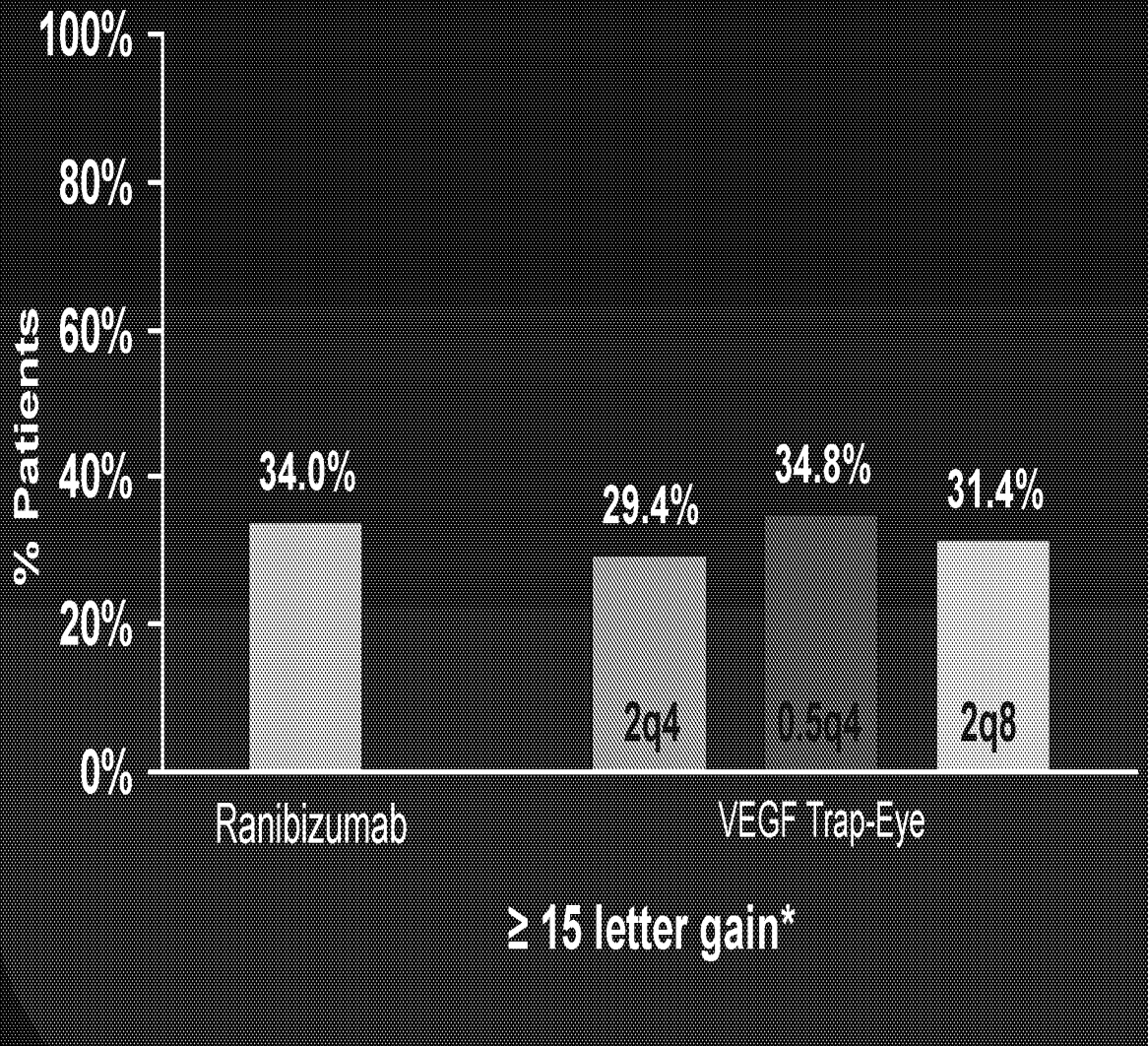


LOCF; full analysis set: Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306


VIEW 1 & 2
Mean Change in Visual Acuity to 1 year
Compared to Baseline
VIEW 1
ETDRS letters
12
10
8
6
4
2
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
10.9* 2q4 (n=304)
8.1 Rq4 (n=304)
7.9† 2q8 (n=301)
6.9† 0.5q4 (n=301)
VIEW 2
ETDRS letters
12
10
8
6
4
2
0
0 4 8 12 16 20 24 28 32 36 40 44 48 52
Week
9.7† 0.5q4 (n=296)
9.4 Rq4 (n=291)
8.9† 2q8 (n=306)
7.6† 2q4 (n=309)
RQ4
2q4
0.5q4
2q8
*P = 0.0054
†P = NS
vs. Rq4

VIEW 2

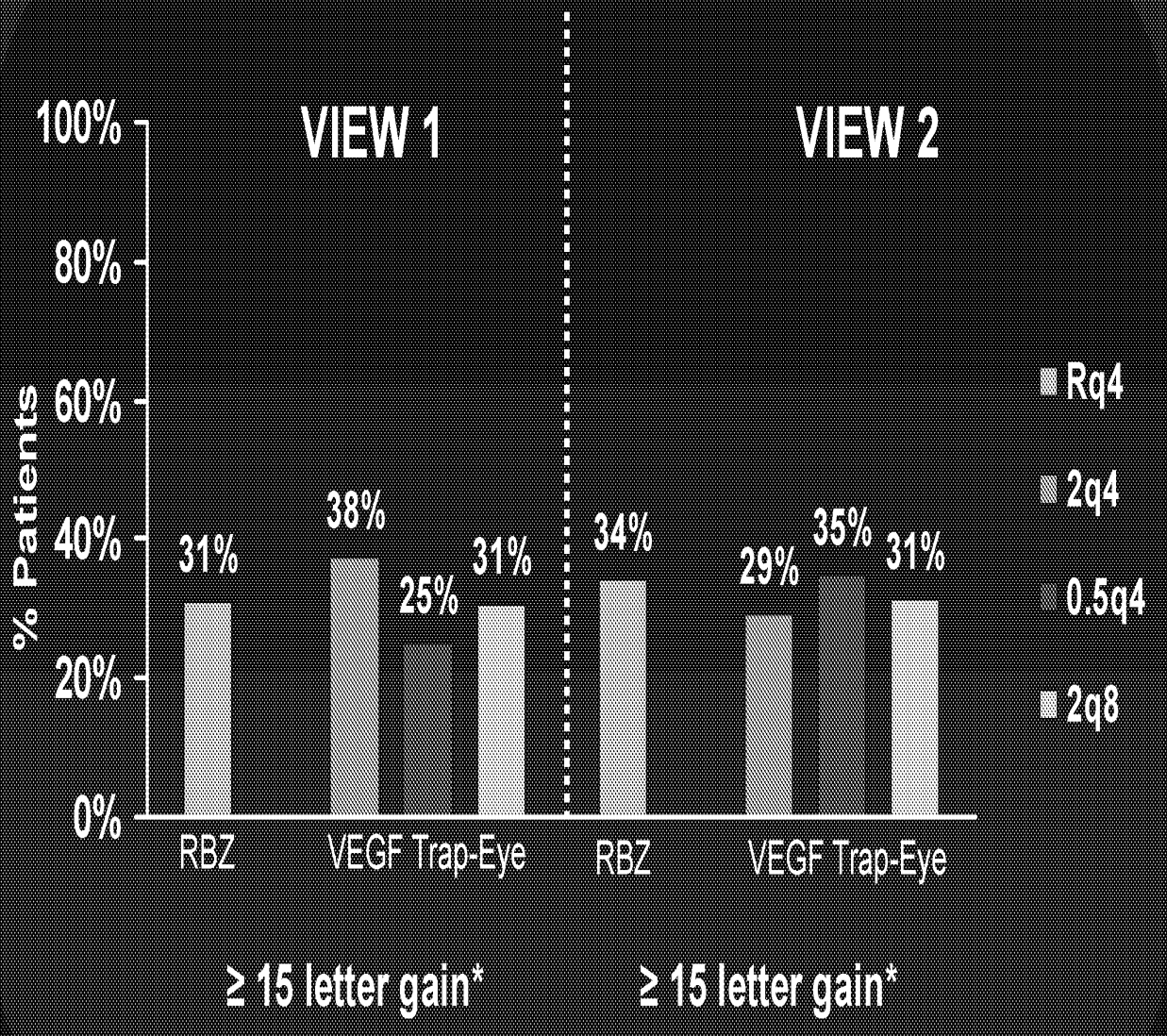
Proportion of Patients Who Gained ≥ 15 letters



*Compared to baseline; LOCF; full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306

VIEW 1 & 2

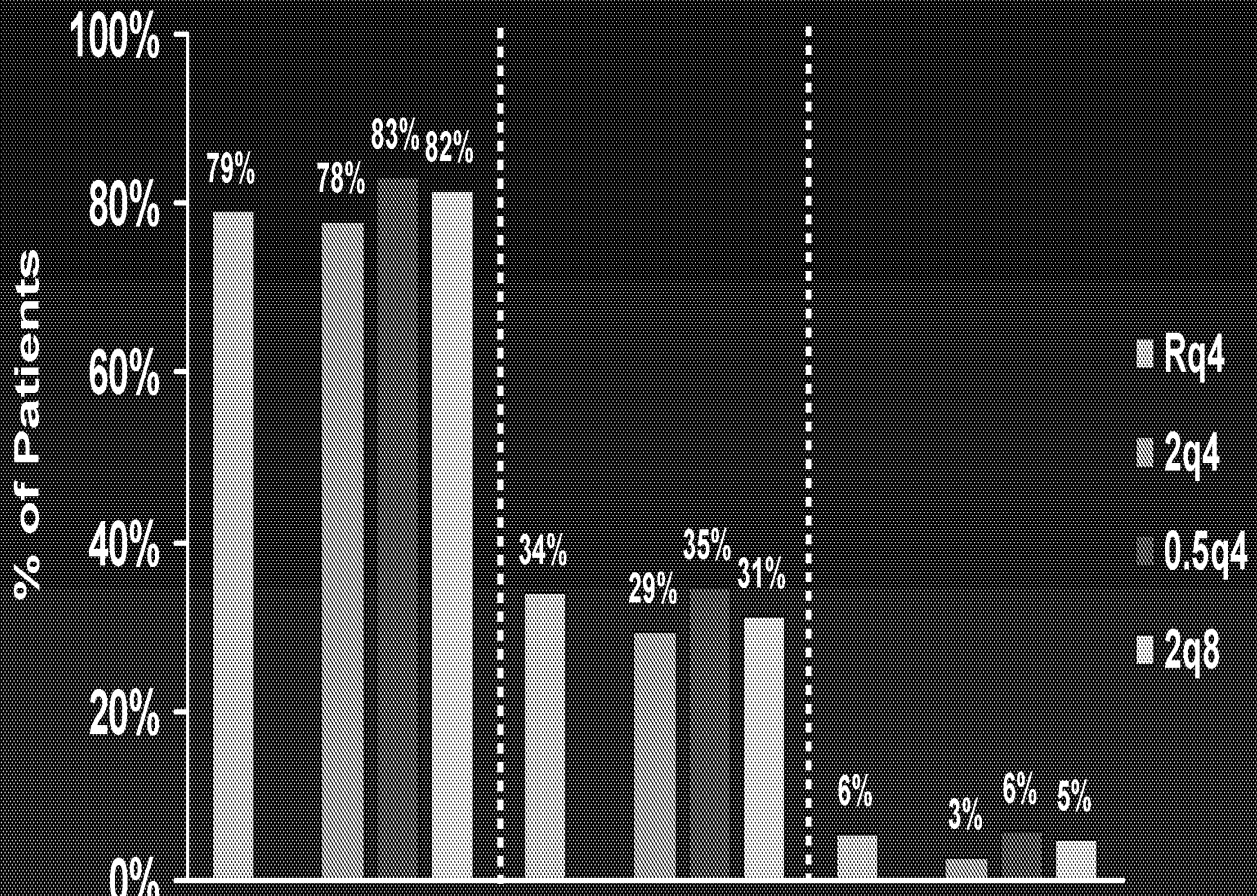
Proportion of Patients Who Gained ≥ 15 letters



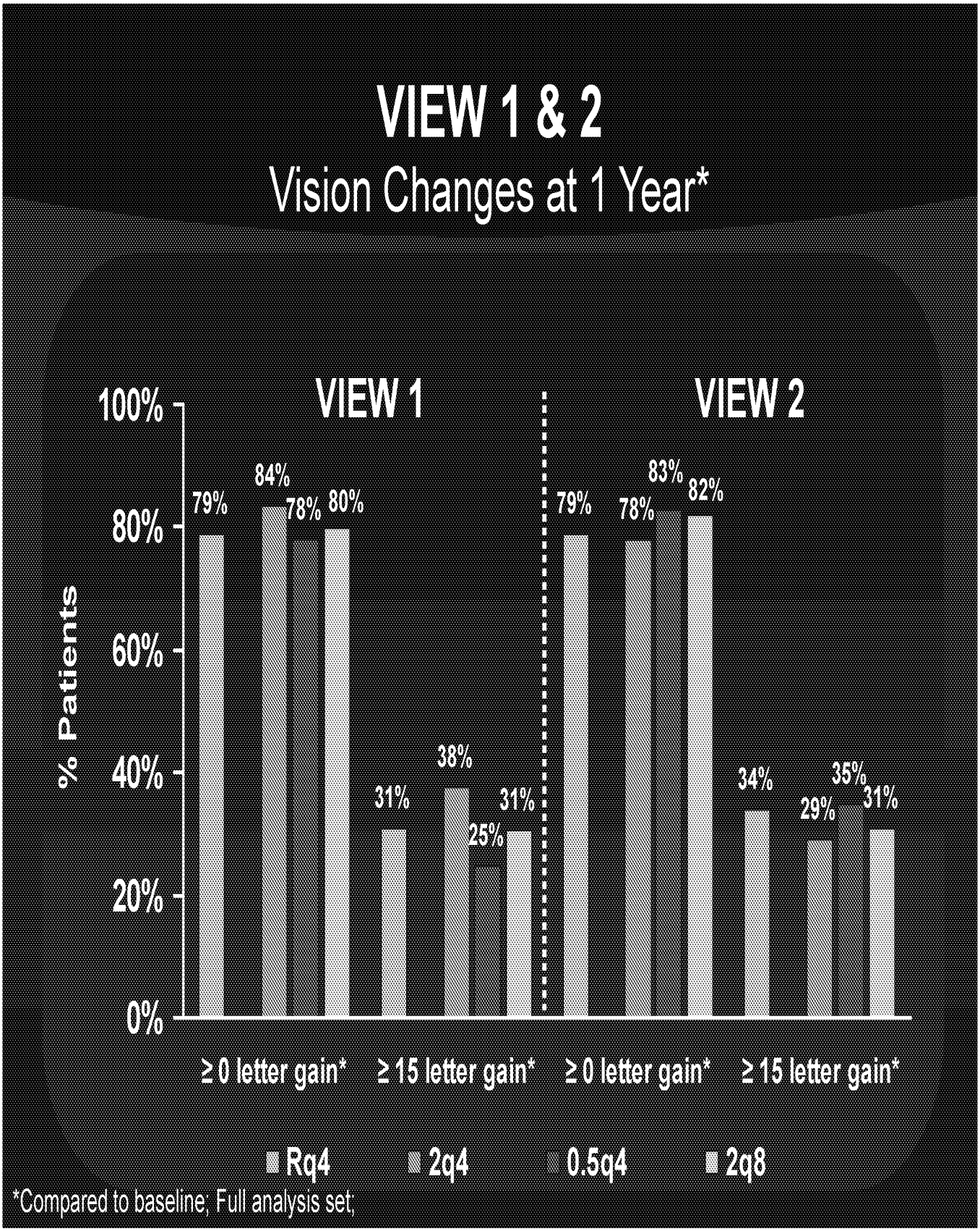
*Compared to baseline; LOCF; FAS;

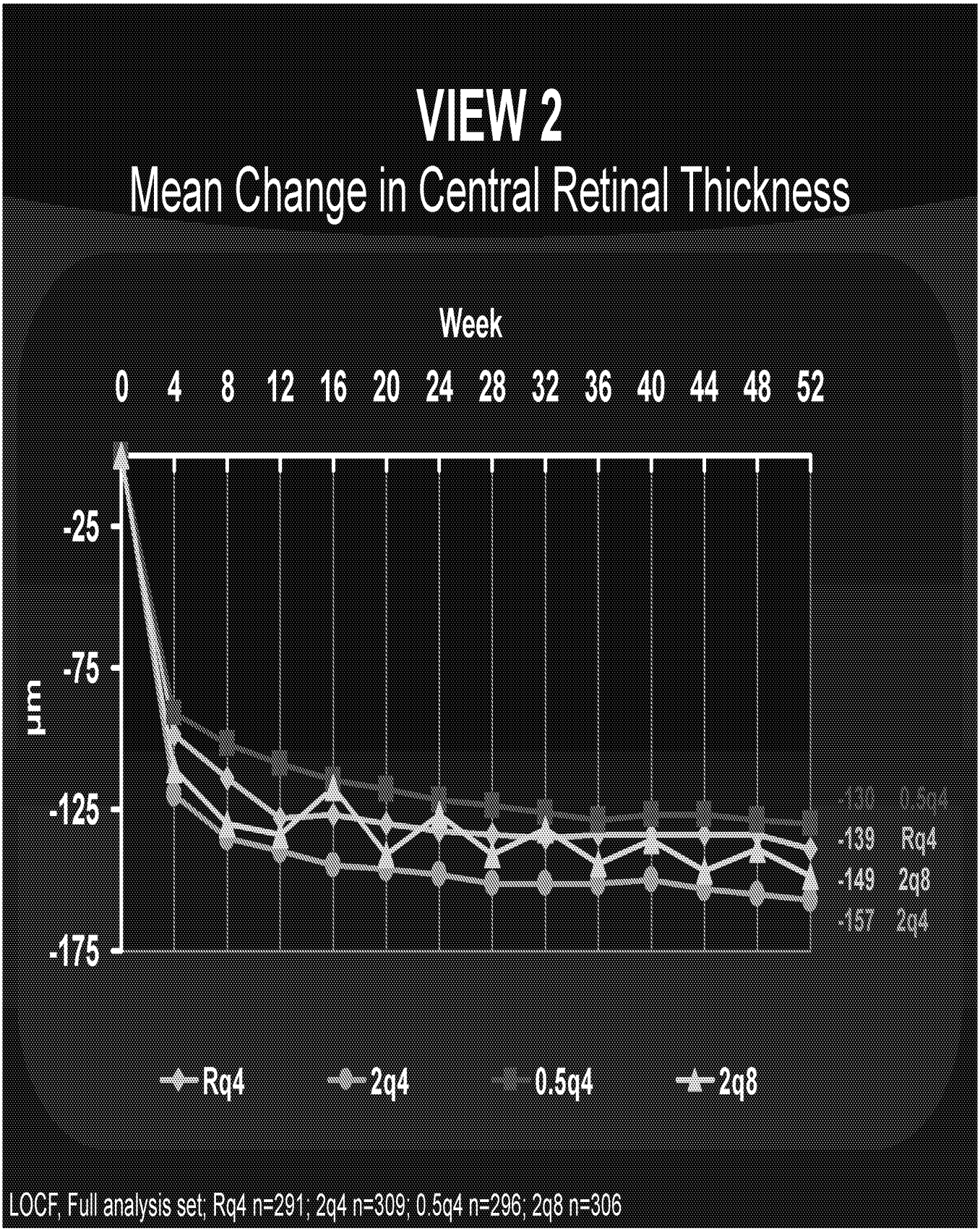
VIEW 2

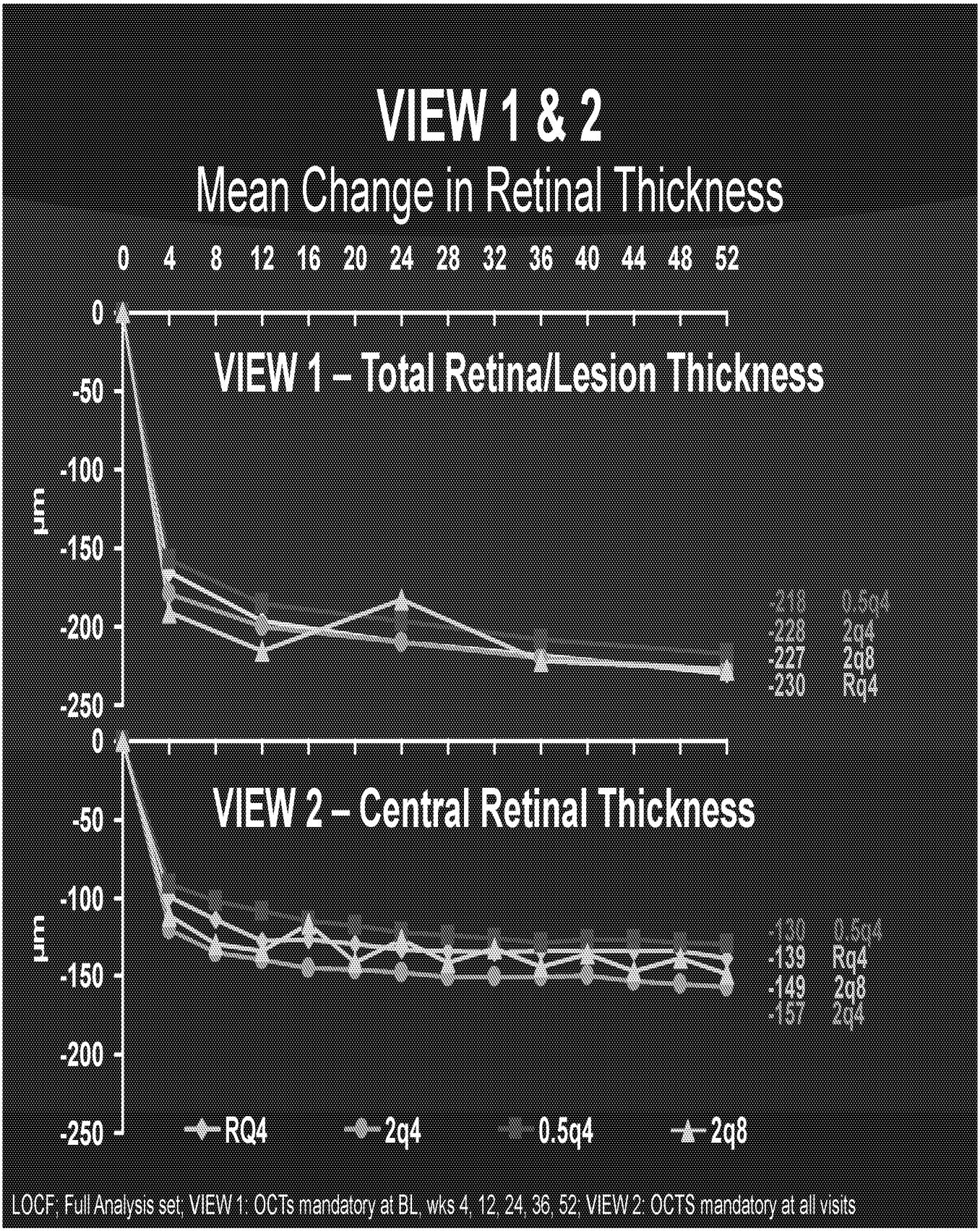
Vision Changes at 1 Year*



*Compared to baseline; LOCF, Full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306


VIEW 1 & 2
Vision Changes at 1 Year*
VIEW 1
VIEW 2
% Patients
100%
80%
60%
40%
20%
0%
79%
84%
78%
80%
31%
38%
25%
31%
79%
78%
83%
82%
34%
29%
35%
31%
≥ 0 letter gain*
≥ 15 letter gain*
≥ 0 letter gain*
≥ 15 letter gain*
Rq4
2q4
0.5q4
2q8
*Compared to baseline; Full analysis set;


VIEW 2
Mean Change in Central Retinal Thickness
Week
0 4 8 12 16 20 24 28 32 36 40 44 48 52
-25
-75
-125
-175
µm
-139 Rq4
-149 2q8
-157 2q4
Rq4
2q4
0.5q4
2q8
LOCF, Full analysis set; Rq4 n=291; 2q4 n=309; 0.5q4 n=296; 2q8 n=306


VIEW 1 & 2
Mean Change in Retinal Thickness
0 4 8 12 16 20 24 28 32 36 40 44 48 52
VIEW 1 – Total Retina/Lesion Thickness
0
-50
-100
-150
-200
-250
µm
-218 0.5q4
-228 2q4
-227 2q8
-230 Rq4
VIEW 2 – Central Retinal Thickness
-130 0.5q4
-139 Rq4
-149 2q8
-157 2q4
RQ4
2q4
0.5q4
2q8
LOCF; Full Analysis set; VIEW 1: OCTs mandatory at BL, wks 4, 12, 24, 36, 52; VIEW 2: OCTS mandatory at all visits



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VIEW 2

Patients with Study Eye Ocular Serious Adverse Events

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
n (safety analysis set)	291	309	297	307	913
# of subjects with at least 1 AE	9 (3.1%)	7 (2.3%)	5 (1.7%)	9 (2.9%)	21 (2.3%)
Endophthalmitis	0	0	0	0	0
Visual acuity reduced	1 (0.3%)	1 (0.3%)	1 (0.3%)	4 (1.3%)	6 (0.7%)
Retinal haemorrhage	1 (0.3%)	2 (0.6%)	1 (0.3%)	1 (0.3%)	4 (0.4%)
Macular degeneration	0	1 (0.3%)	0	1 (0.3%)	2 (0.2%)
Intraocular pressure increased	0	0	1 (0.3%)	1 (0.3%)	2 (0.2%)
Cataract	1 (0.3%)	1 (0.3%)	0	1 (0.3%)	2 (0.2%)
Retinal pigment epithelial tear	1 (0.3%)	0	1 (0.3%)	1 (0.3%)	2 (0.2%)
Cataract nuclear	0	1 (0.3%)	0	0	1 (0.1%)
Choroidal detachment	0	0	0	1 (0.3%)	1 (0.1%)
Macular cyst	0	0	0	1 (0.3%)	1 (0.1%)
Macular hole	0	0	1 (0.3%)	0	1 (0.1%)
Macular scar	0	1 (0.3%)	0	0	1 (0.1%)
Retinal detachment	1 (0.3%)	0	1 (0.3%)	0	1 (0.1%)
Retinal pigment epitheliopathy	0	1 (0.3%)	0	0	1 (0.1%)
Cataract cortical	1 (0.3%)	0	0	0	0
Posterior capsule opacification	2 (0.7%)	0	0	0	0
Retinal degeneration	1 (0.3%)	0	0	0	0
Hyphaema	1 (0.3%)	0	0	0	0

VIEW 2

Deaths

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	291	309	297	307	913
All Deaths*	2 (0.7%)	3 (1.0%)	2 (0.7%)	2 (0.7%)	7 (0.8%)
Myocardial Infarction	1	1*	1	0	2
Cerebrovascular Accident	0	1*	0	0	1
Pyrexia	0	1	0	0	1
Cardiopulmonary Failure	0	1	0	0	1
Cancer Related	1	0	0	1	1
Cardiac Arrest	0	0	0	1	1
Unknown	0	0	1	0	1

* One patient experienced 2 events leading to death

VIEW 2

Patients with APTC Events through 1 Year

	RBZ 0.5q4 0.5 mg q4 wks	VTE 2q4 2 mg q4 wks	VTE 0.5q4 0.5 mg q4 wks	VTE 2q8 2 mg q8 wks	All VTE
N (safety analysis set)	291	309	297	307	913
Any APTC event	5 (1.7%)	4 (1.3%)	5 (1.7%)	8 (2.6%)	17 (1.9%)
Vascular Deaths	1 (0.3%)	1 (0.3%)	2 (0.7%)	1 (0.3%)	4 (0.4%)
Non Fatal MI	2 (0.7%)	2 (0.6%)	2 (0.7%)	5 (1.6%)	9 (1.0%)
Non Fatal Stroke[b]	2 (0.7%)	1 (0.3%)	1 (0.3%)	2 (0.7%)	4 (0.4%)

Note: Percentage values (rounded to one decimal place) were calculated by author

[b]Non-fatal hemorrhagic and ischemic strokes were combined to one category

VIEW 1 & 2

% Patients with APTC Events through 1 Year

VIEW 1

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	304	304	304	303	911
Any APTC event	5 (1.6)	2 (0.7)	7 (2.3)	6 (2.0)	15 (1.6)
Vascular Deaths	1 (0.3)	0	1 (0.3)	4 (1.3)	5 (0.5)
Non Fatal MI	4 (1.3)	1 (0.3)	4 (1.3)	1 (0.3)	6 (0.7)
Non Fatal Stroke[a]	0	1 (0.3)	2 (0.7)	1 (0.3)	4 (0.4)

VIEW 2

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	291	309	297	307	913
Any APTC event	5 (1.7)	4 (1.3)	5 (1.7)	8 (2.6)	17 (1.9)
Vascular Deaths	1 (0.3)	1 (0.3)	2 (0.7)	1 (0.3)	4 (0.4)
Non Fatal MI	2 (0.7)	2 (0.6)	2 (0.7)	5 (1.6)	9 (1.0)
Non Fatal Stroke[b]	2 (0.7)	1 (0.3)	1 (0.3)	2 (0.7)	4 (0.4)

[a]All non fatal strokes were ischemic in nature

[b]Includes hemorrhagic and ischemic strokes

VIEW 1 & 2

Hypertension

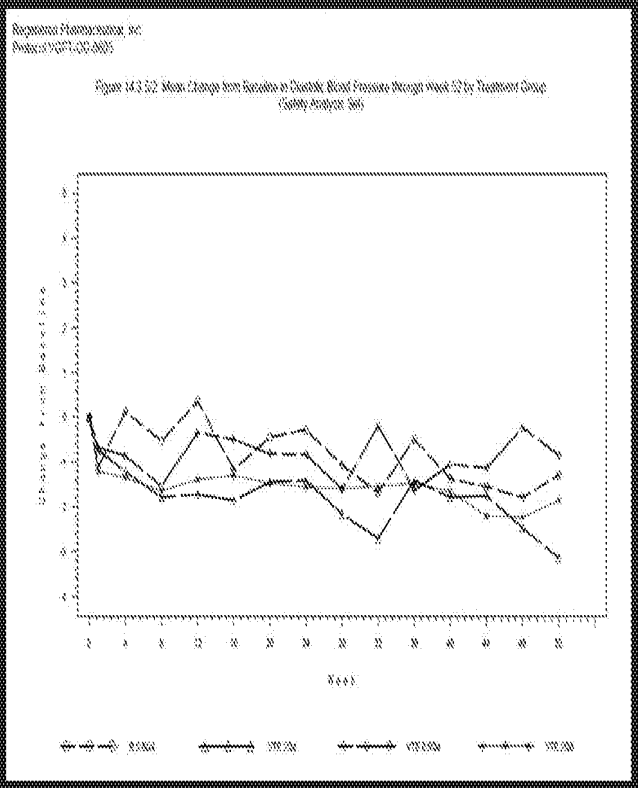
VIEW 1

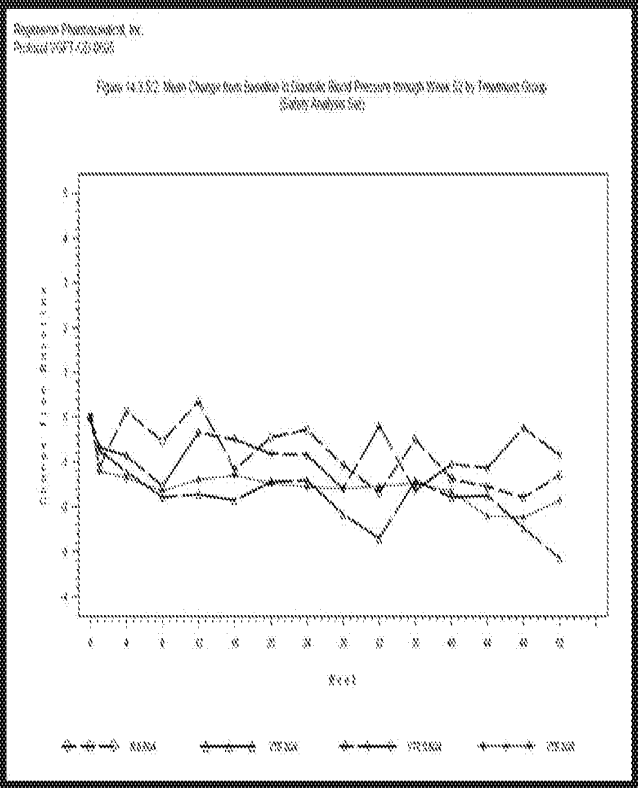
	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	304	304	304	303	911
# with at least 1 Hypertension AE	29 (9.5%)	25 (8.2%)	26 (8.6%)	31 (10.2%)	82 (9.0%)

VIEW 2

	RBZ 0.5q4	VTE 2q4	VTE 0.5q4	VTE 2q8	All VTE
N (safety analysis set)	291	309	297	307	913
# with at least 1 Hypertension AE	29 (10.0%)	31 (10.0%)	22 (7.4%)	28 (9.1%)	81 (8.9%)

Mean change in blood pressure over 12 months





systolic

diastolic

VIEW 1 & 2

Conclusion: Efficacy

- Results with all VEGF Trap-Eye regimens were shown to be statistically non-inferior with clinically equivalent outcomes to monthly ranibizumab treatment in two independent trials

- The regimen applying 2 mg VEGF Trap-Eye at every two month intervals following a loading dose demonstrated similar functional and anatomical efficacy compared to monthly ranibizumab

VIEW 1 & 2

Conclusion: Safety

- All VEGF Trap-Eye treatment arms in both studies demonstrated a favorable safety profile in a typical AMD population
- VTE was generally safe and well-tolerated without differences compared to monthly ranibizumab in ocular and non-ocular AEs
- No endophthalmitis was reported in VIEW 2
- APTC-defined ATE events were rare and similar among the groups
  - Vascular deaths occurred < 1 %

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Biocon Exhibit 1012 - Page 5265

Conclusions

With the introduction of VEGF Trap-Eye
another important step is taken
in the treatment of neovascular AMD
in respect to

- Efficacy
- Practicality
- Multi-ethnicity

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VEGF Trap – Eye
CLEAR-IT 2 Final Primary Endpoint Results

A Phase 2, Randomized, Controlled Dose- and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration

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Disclosures

- Commercial relationships
  - J. Heier, Regeneron financial support
- Trial registration
  - www.clinicaltrials.gov (NCT00320788)

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Angiogenesis Inhibition via VEGF Blockade Unmet Medical Needs Remain Despite Major Advances in Treatment of Wet AMD

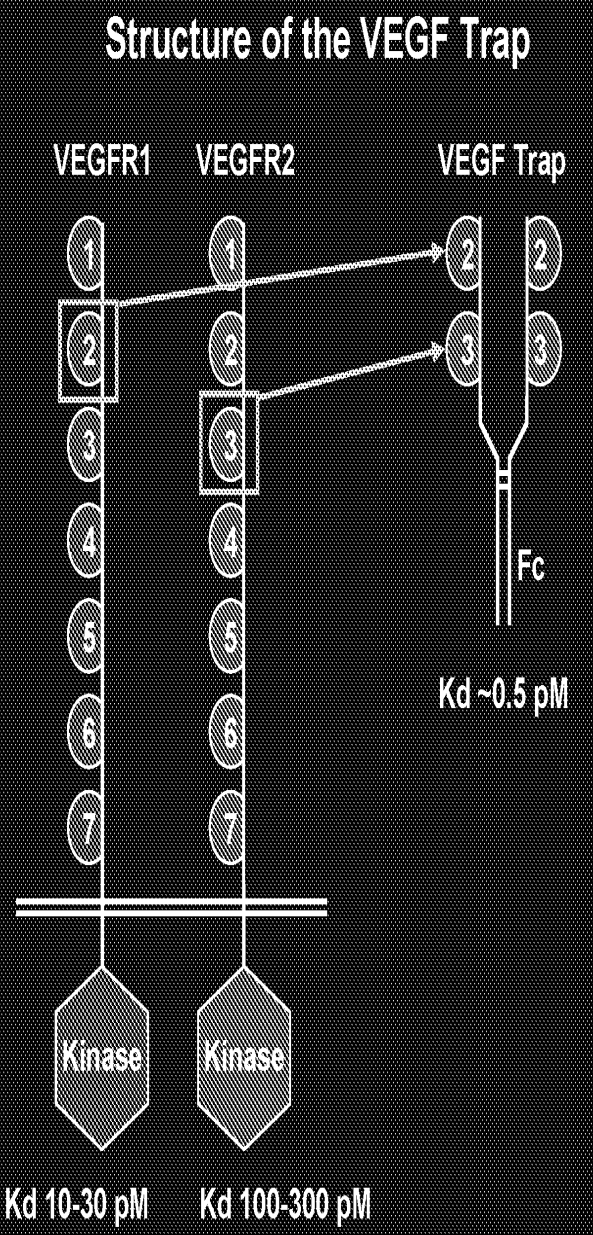
- Ranibizumab (LUCENTIS®*) represents a major advance in wet AMD treatment
  - The approved regimen of ranibizumab in the U.S., 0.5 mg administered monthly, resulted in the following results at 1 year:[1]
    - Prevention of moderate vision loss in 95-96% of patients
    - A ≥15 letter (3-line) gain in 34- 40% of patients
    - Mean improvement in visual acuity of 7.2-11.3 letters (~6-10 at month 4)
    - Vision of ≥20/40 in 39-40% of patients
    - Vision of ≤20/200 in only 12-16% of patients
- A clinical need remains for an agent that can further improve vision
  - Further improvement in visual acuity
  - More patients with vision of ≥20/40
  - Fewer patients with vision of ≤20/200
- A clinical need remains for an agent that improves and maintains visual acuity with a dosing schedule requiring less than monthly injections

* LUCENTIS® is a registered trademark of GENENTECH, Inc

1 Rosenfeld, et al., *N Engl. J Med.*, 2006 355(14):1419-31; Brown, et al., *N Engl. J Med.*, 2006 355(14):1432-44

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VEGF Trap-Eye*: A Unique VEGF Blocker



- Fusion protein of key domains from human VEGF receptors 1 and 2 with human IgG Fc
- Contains all human amino acid sequences
- High affinity and binds VEGF more tightly than native receptors or monoclonal antibody
- Blocks all VEGF-A isoforms and Placental Growth Factor (PlGF)
- Penetrates all layers of the retina (MW ~110,000)

*VEGF Trap–Eye is specially purified and formulated for intravitreal injection.

IgG=immunoglobulin G; MW=molecular weight; VEGF=vascular endothelial growth factor; VEGFR=vascular endothelial growth factor receptor.

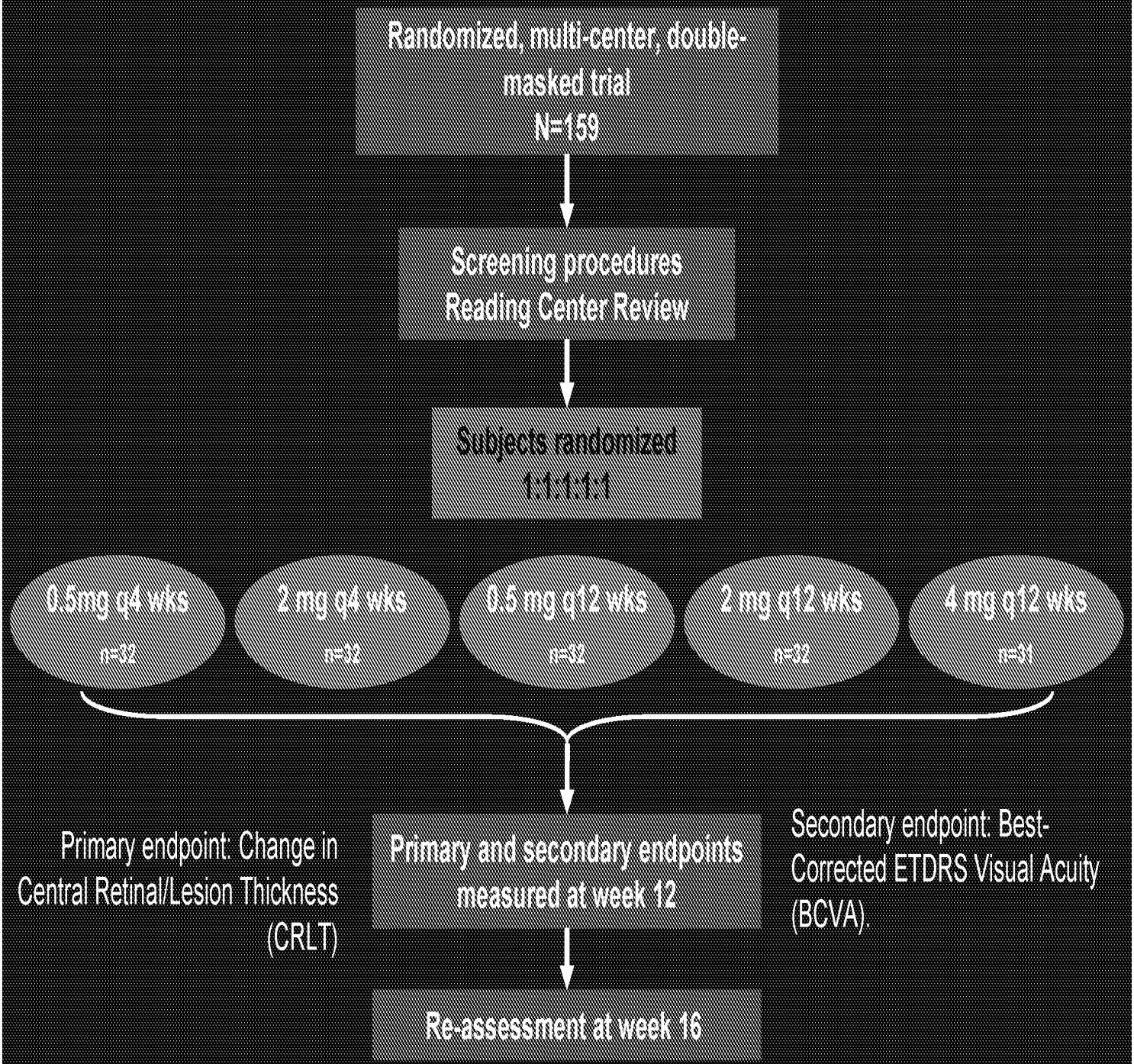
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CLEAR-IT 2 Study Objectives

- Primary objectives:
  - Assess the effect of intravitreal VEGF Trap-Eye on retinal thickness
  - Assess ocular and systemic safety and tolerability of repeated IVT doses of VEGF Trap-Eye in wet AMD
- Secondary objective:
  - Assess the effect of IVT VEGF Trap-Eye on best-corrected visual acuity in ETDRS letters

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Study Design



Primary endpoint: Change in Central Retinal/Lesion Thickness (CRLT)

Secondary endpoint: Best-Corrected ETDRS Visual Acuity (BCVA).

Patients were re-dosed at week 12. PRN dosing scheduled allowed beginning week 16.

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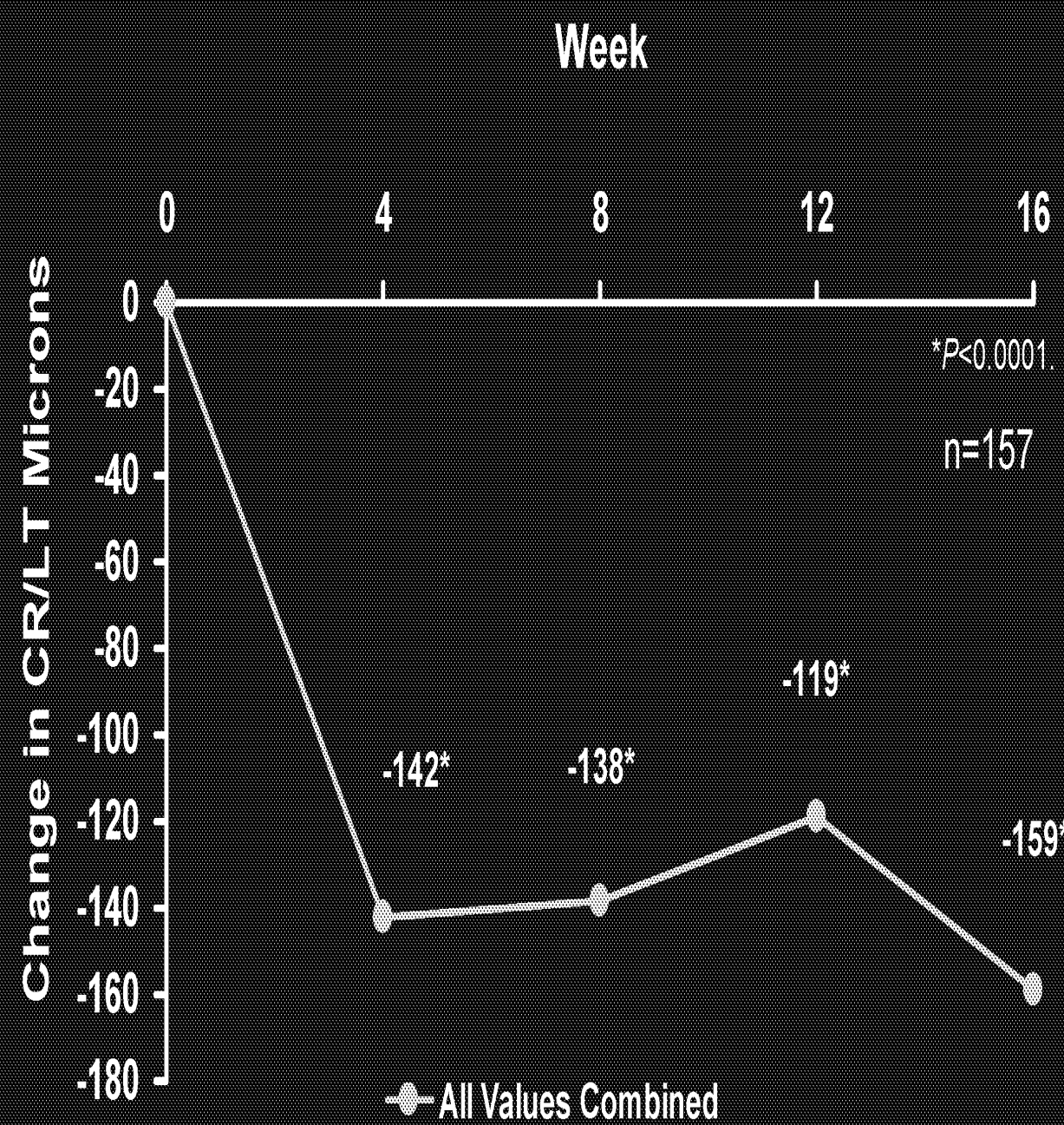
Baseline Characteristics

(N=157*)	Mean	Range
Age (years)	78.2	53-94
Gender (%M:%F)	38:62	
Disease Duration (months)	3.9	0-67
Lesion Type: number (%)		
Classic	30 (19.1)	
Predominantly Classic	30 (19.1)	
Minimally Classic	37 (23.6)	
Occult Lesions	60 (38.2)	
Disease Status		
Central Retinal/Lesion Thickness	456µm	186-1316µm
Foveal Thickness	327µm	116-1081µm
ETDRS BCVA (Letters)	56	27-83

*N=159 randomized; N=157 treated.

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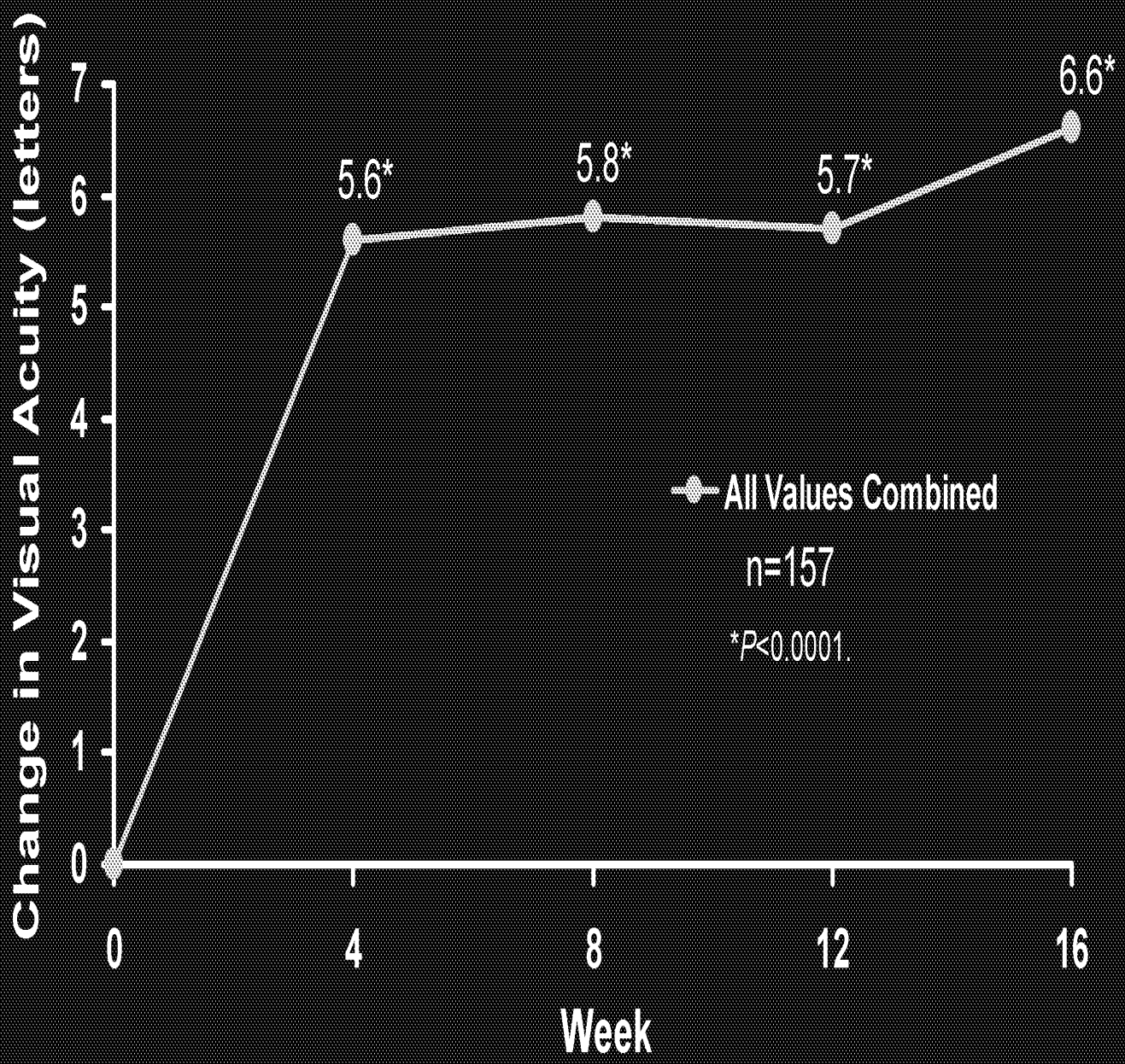
Mean Change in Central Retinal Thickness: Significantly Improved vs Baseline at All Time Points



Posterior Pole Scans, LOCF analysis

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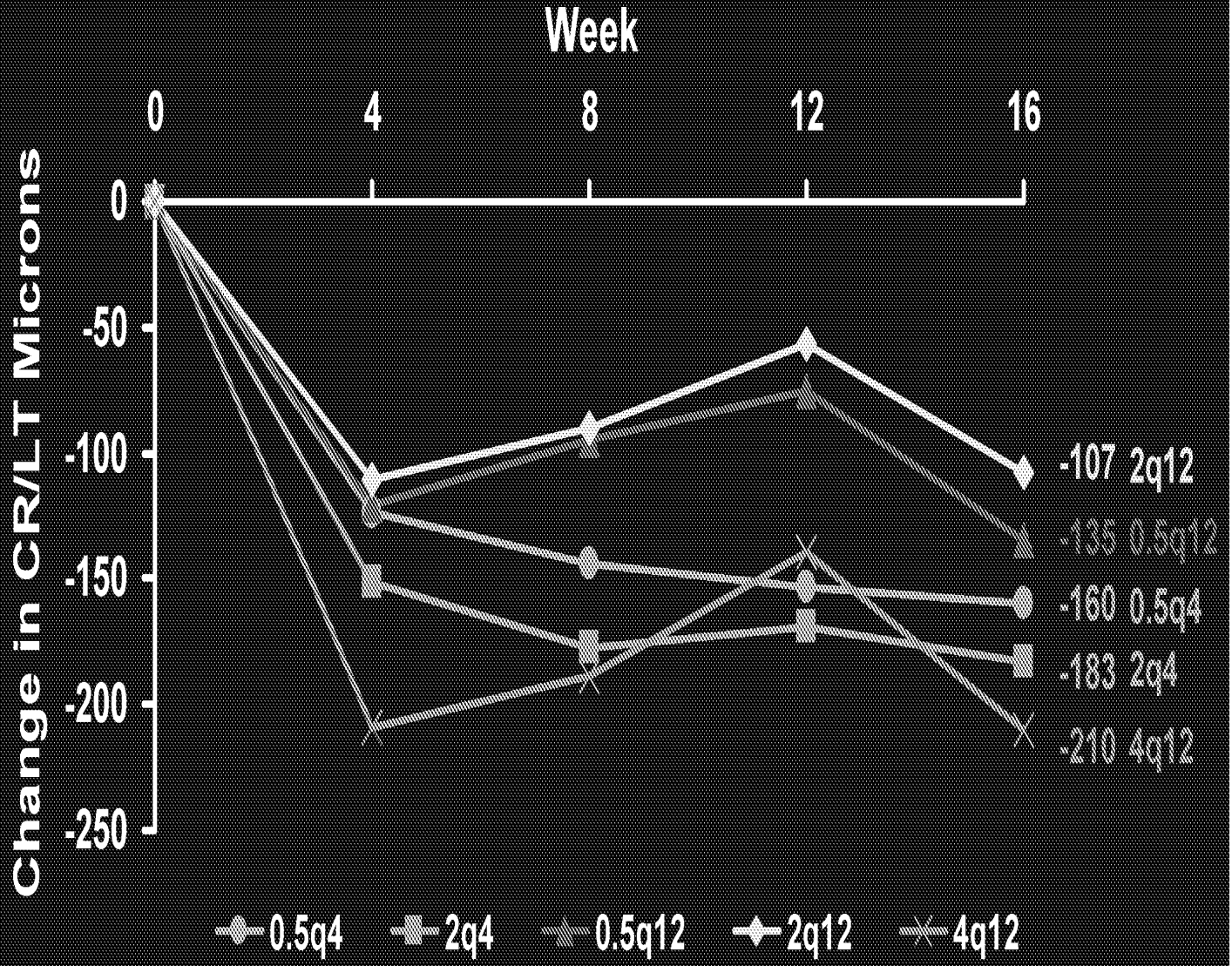
Mean Change in Visual Acuity: Significantly Improved vs Baseline at All Time Points



LOCF analysis

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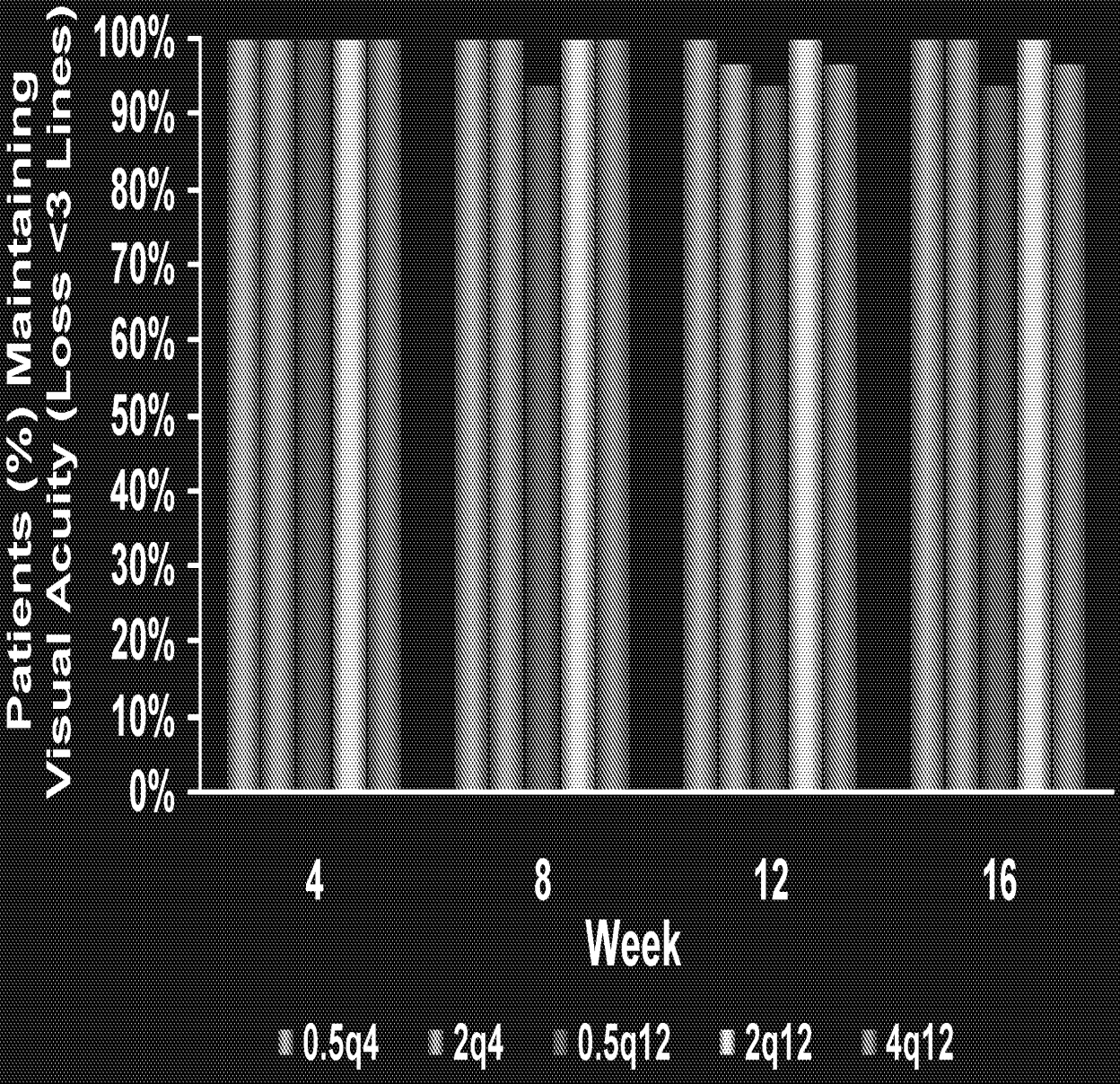
Mean Change in Retinal Thickness: Improved in All Dosing Arms; Monthly Dosing More Consistent in Effect



Posterior Pole Scans, LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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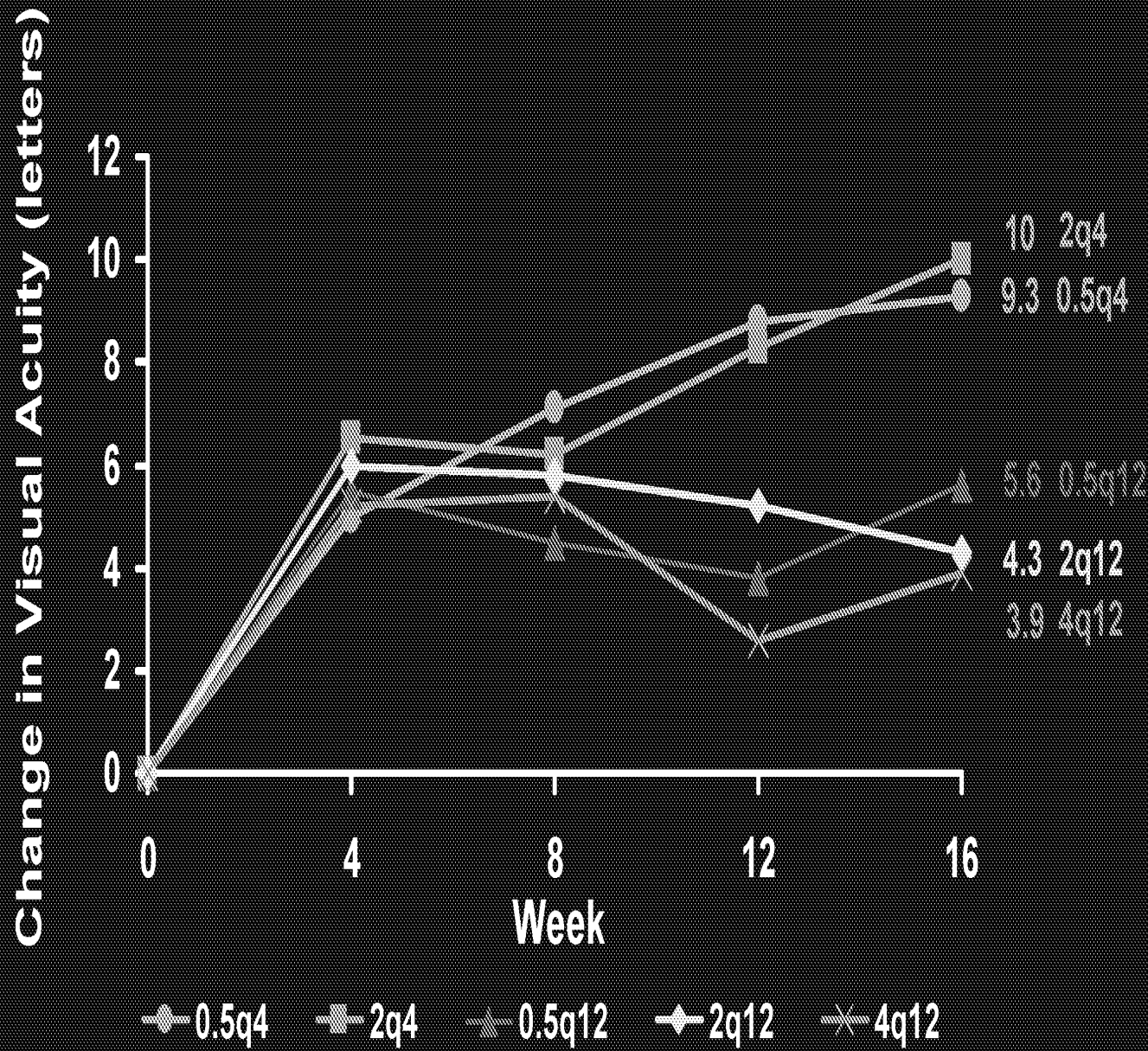
Maintenance of Visual Acuity: Maintained in All Dosing Arms



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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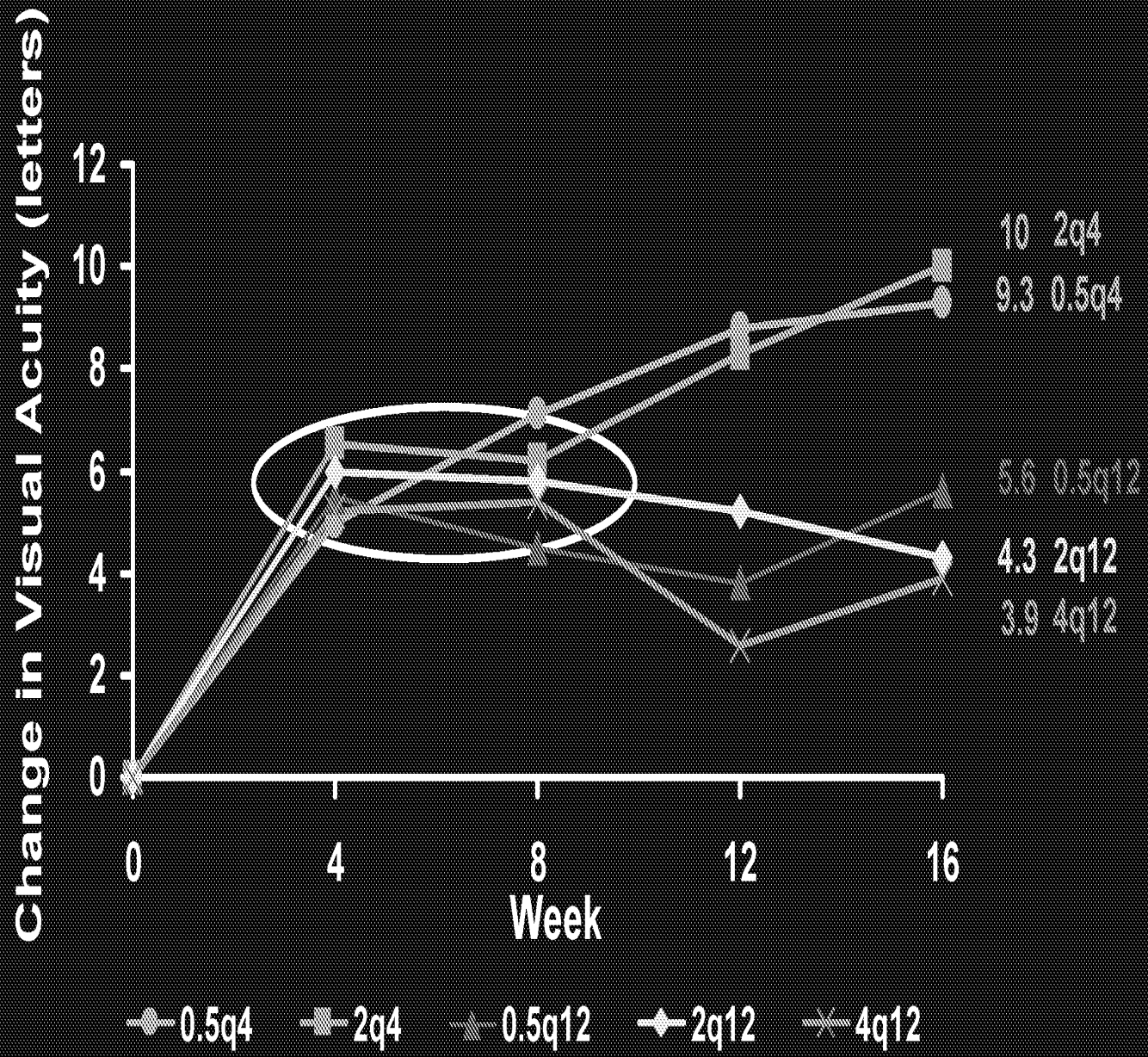
Mean Change in Visual Acuity: Improved in All Dosing Arms; Monthly Dosing Continued to Improve Vision out to Week 16



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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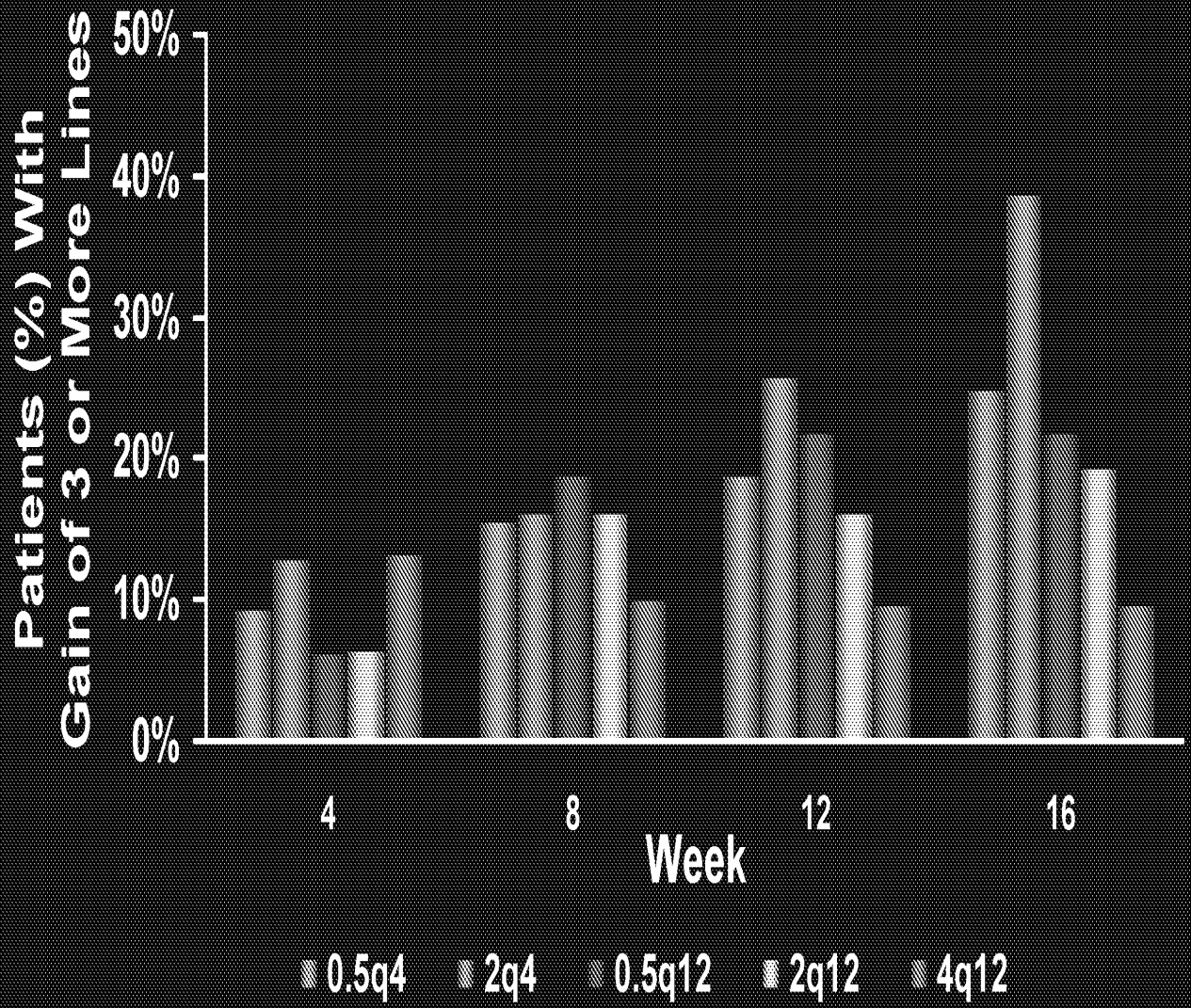
Mean Change in Visual Acuity: Maintained at 8 Weeks With a Single Dose, and With Monthly Dosing



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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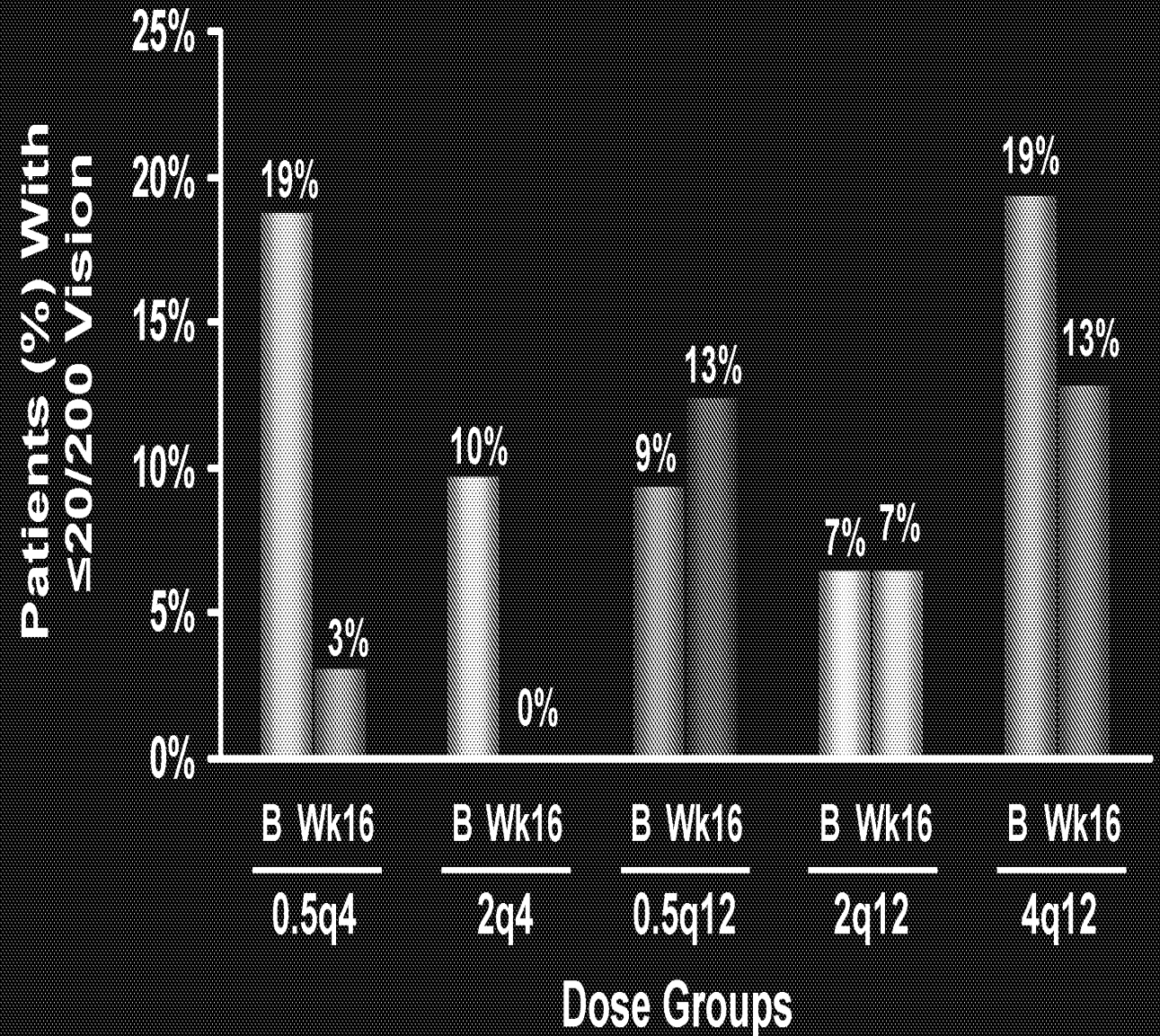
Improvement of ≥3 Lines of Visual Acuity: Improved With All Doses



LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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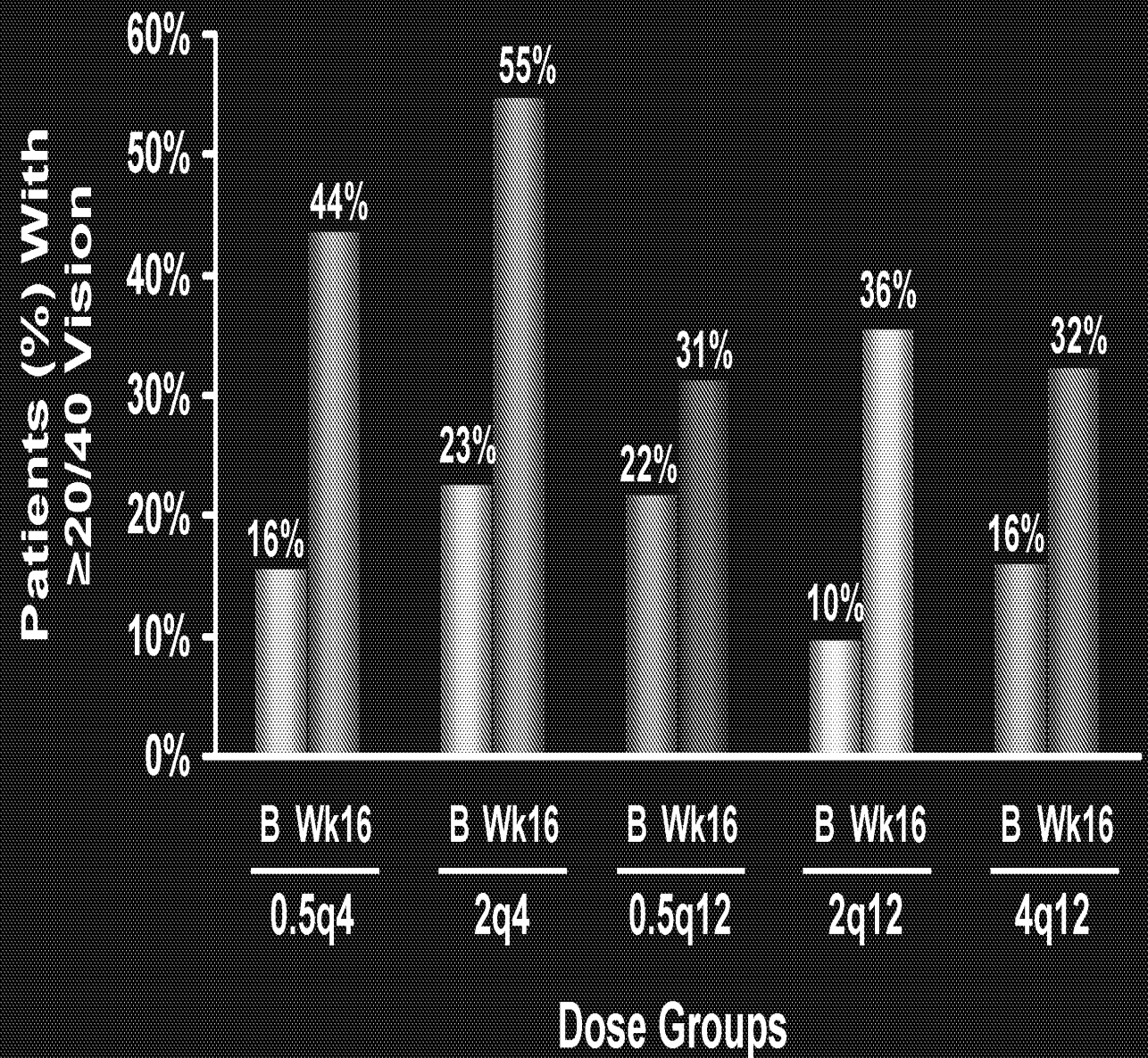
Proportion of Patients With ≤20/200 Vision Decreased With Monthly Dosing



B=baseline. LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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Proportion of Patients With ≥20/40 Vision Increased in All Dosing Arms



B=baseline. LOCF analysis. 0.5q4 and 0.5q12: n=32; 2q4, 2q12, and 4q12: n=31

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Safety: Generally Well-Tolerated

- No ocular Serious Adverse Events (SAE) reported in study eyes
- No reports of clinically significant intraocular inflammation
- No incidence of endophthalmitis
- No drug-related systemic SAEs
- Non drug-related systemic SAEs:
  - 1 incident of angina pectoris (2q4 group)
  - 1 incident of congestive heart failure (0.5q4 group)
  - 1 incident of coronary artery disease (2q4 group)

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Safety: Treatment-Emergent Ocular Adverse Events Reported in > 5 Patients

Study Eye, All Groups Combined

Adverse Event	Number (N=157)	Percent (%)
Conjunctival Hemorrhage	38	24.2
Increased IOP (transient post injection)	21	13.4
Retinal Hemorrhage	13	8.3
Eye Pain	11	7.0
Vitreous Detachment	11	7.0
Detachment of Retinal Pigment Epithelium	9	5.7
Visual Disturbance	9	5.7
Visual Acuity Reduced (patient reported)	7	4.5
Retinal Pigment Epitheliopathy	6	3.8
Retinal Oedema	6	3.8

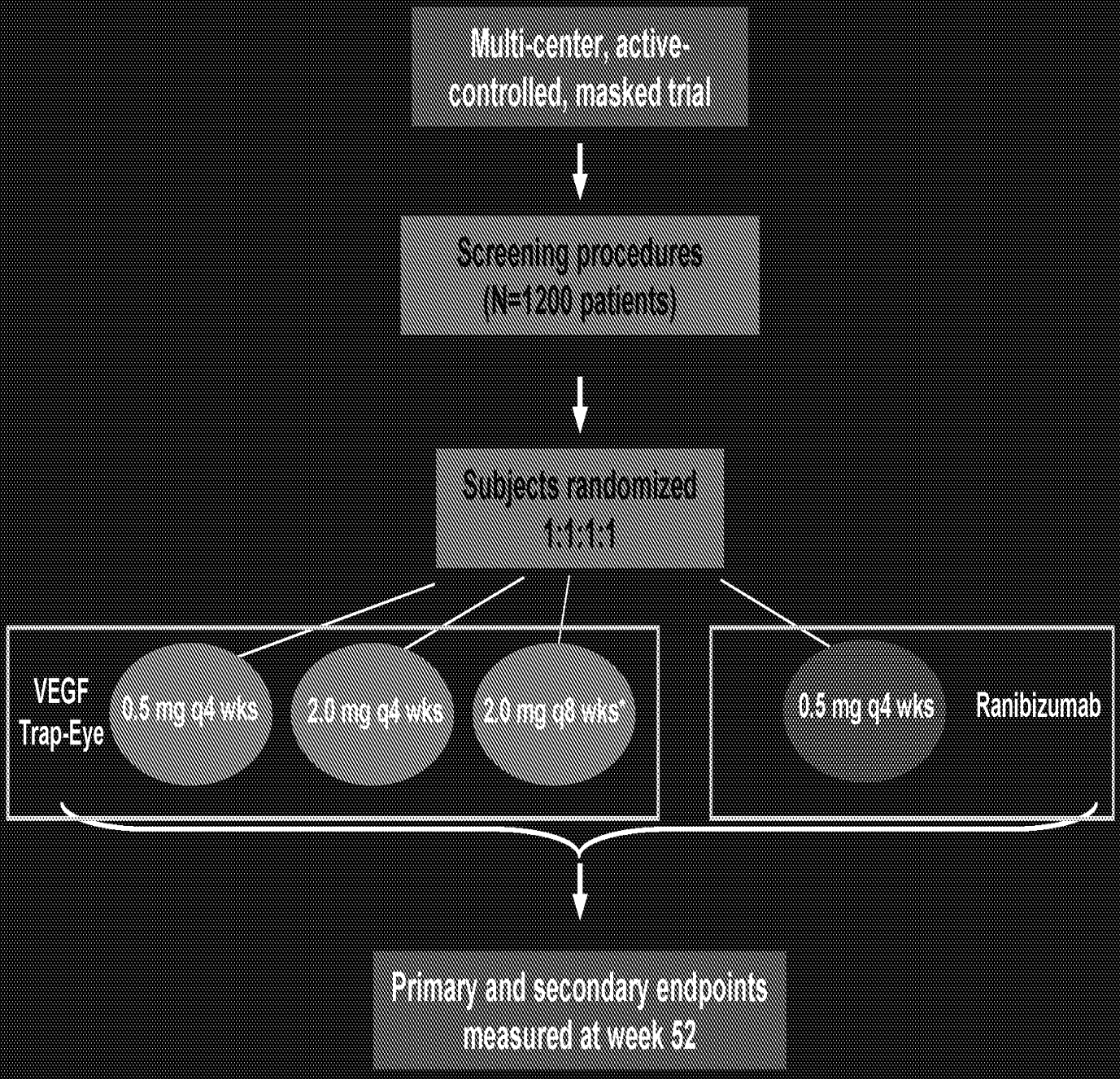
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Conclusions

- VEGF Trap-Eye significantly reduced retinal thickness from baseline, the primary study endpoint ($p<0.0001$)
- VEGF Trap also significantly improved visual acuity from baseline ($p<0.0001$)
- VEGF Trap-Eye 0.5 mg and 2 mg dosed every 4 weeks demonstrated the most improvement in retinal thickness and visual acuity at the 12-week primary endpoint and continued to show improvement at 16 weeks
  - 160-183 micron decrease in retinal thickness
  - 9.3-10.0 letter improvement in visual acuity
  - Reduction in number of patients with $\leq$20/200 vision to 0-3%
  - Increase in number of patients with $\geq$20/40 vision to 44-55%
- While quarterly dosing significantly improved retinal thickness and visual acuity versus baseline at all times, the effect was not as robust as with monthly dosing
  - A single dose maintained its effect on visual acuity out to 8 weeks
- Safety profile was predictable with no drug-related systemic side effects and no significant ocular inflammation

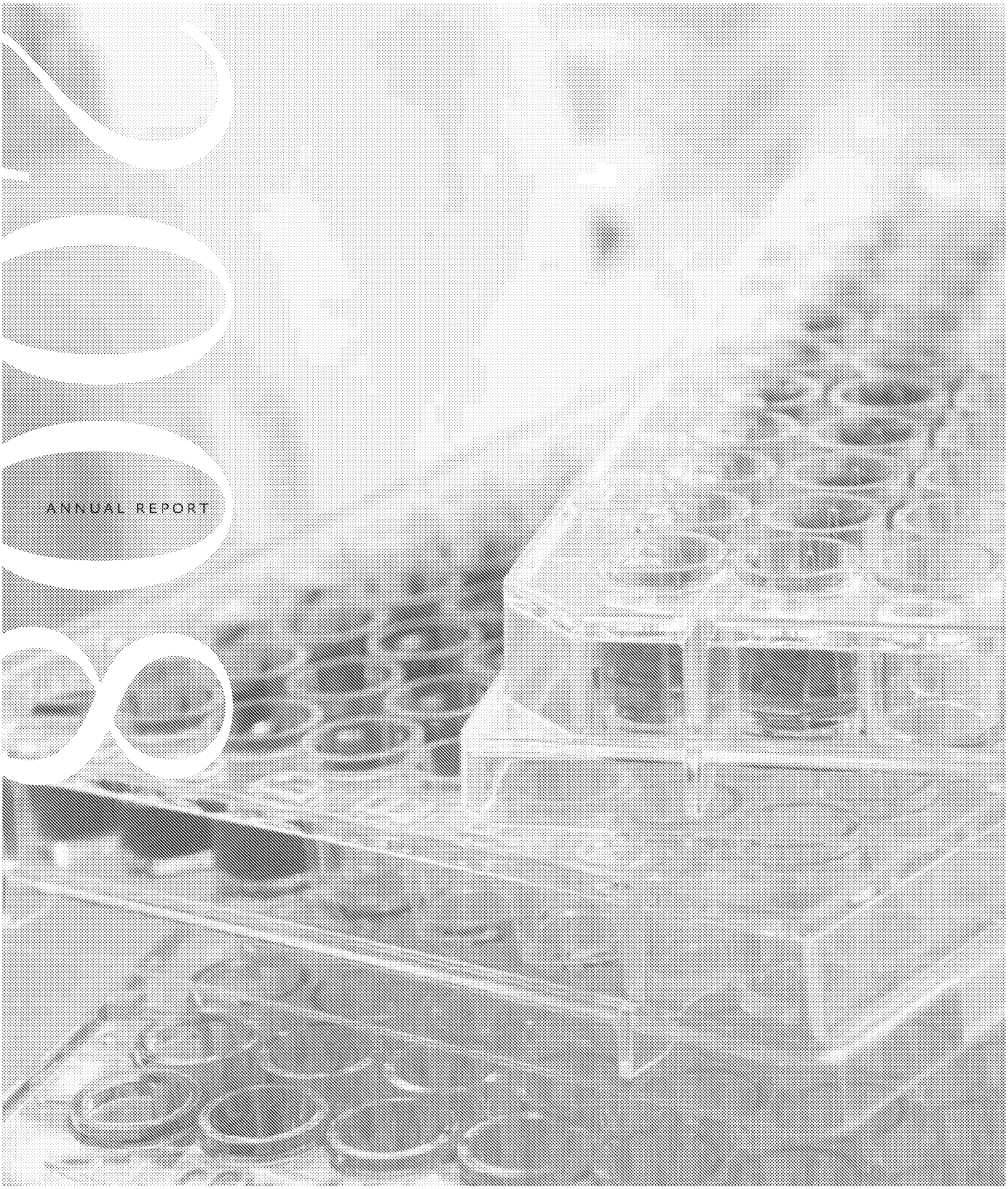
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VIEW 1 Phase 3 Study Design
Currently Enrolling Patients



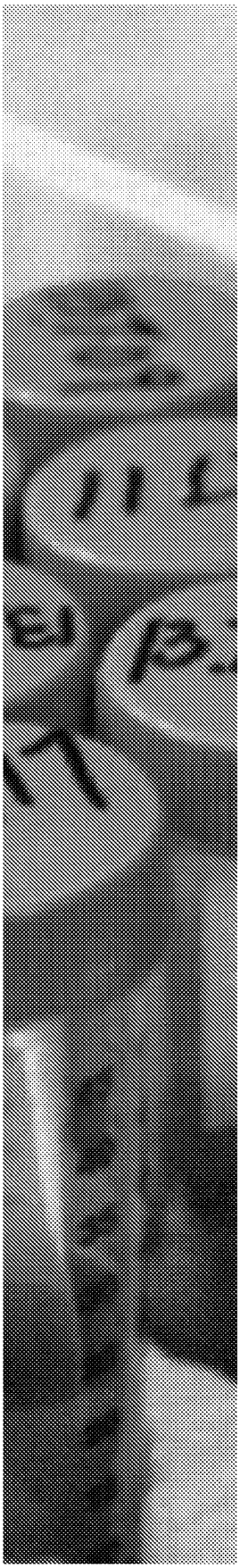
*After a 3-month monthly loading dose period.

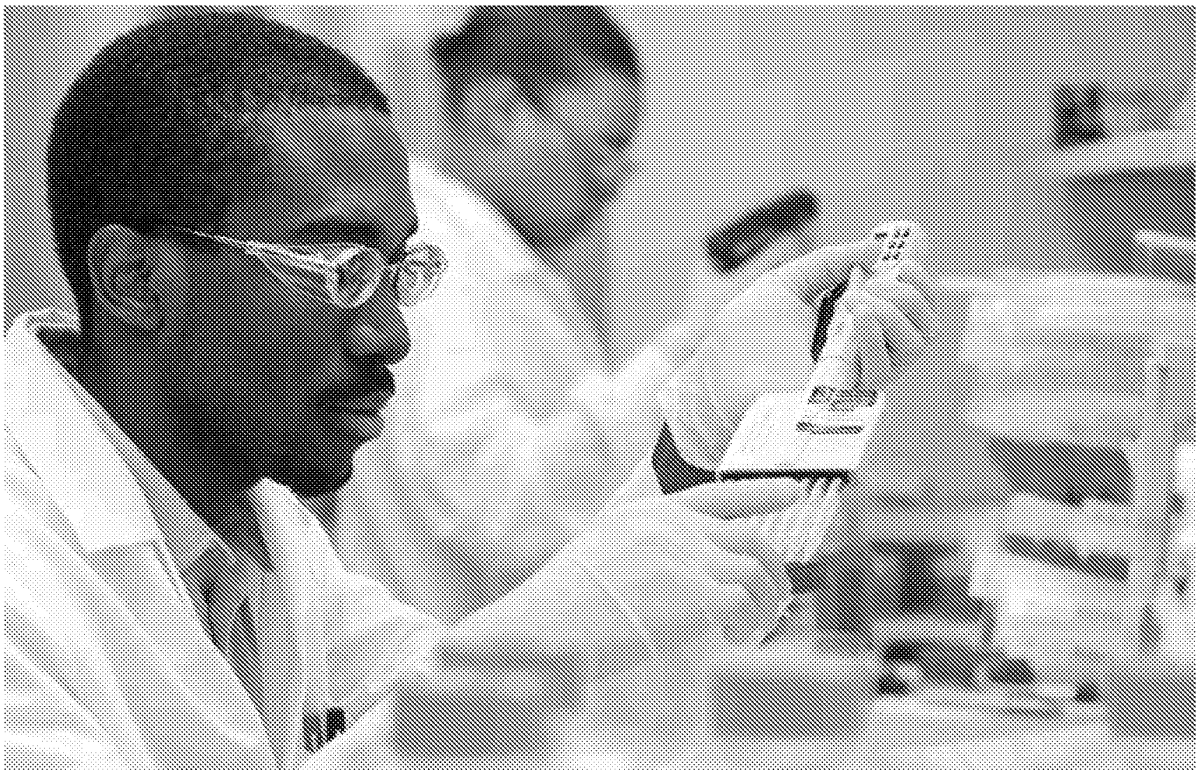
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REGENERON

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The Numbers...and Beyond

During 2008, Regeneron continued to execute on our long-term vision: to discover, develop, and commercialize medicines for the treatment of serious medical conditions. Much of our progress can be charted in numbers: sales of our first marketed product; clinical trials initiated and underway; new molecules discovered and advanced into development; and new employees brought on board to help our company move forward. But some things can't be quantified: the passion of our people for the work they do; the impact of ARCALYST® (rilonacept) Injection for Subcutaneous Use, our first marketed product, on the well-being of patients with Cryopyrin-Associated Periodic Syndromes or CAPS; and the potential of our pipeline to improve health for patients suffering from serious diseases.

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From 1 marketed product to 13 programs to $527 million in cash at year-end 2008, Regeneron's progress can be measured in numbers large and small.

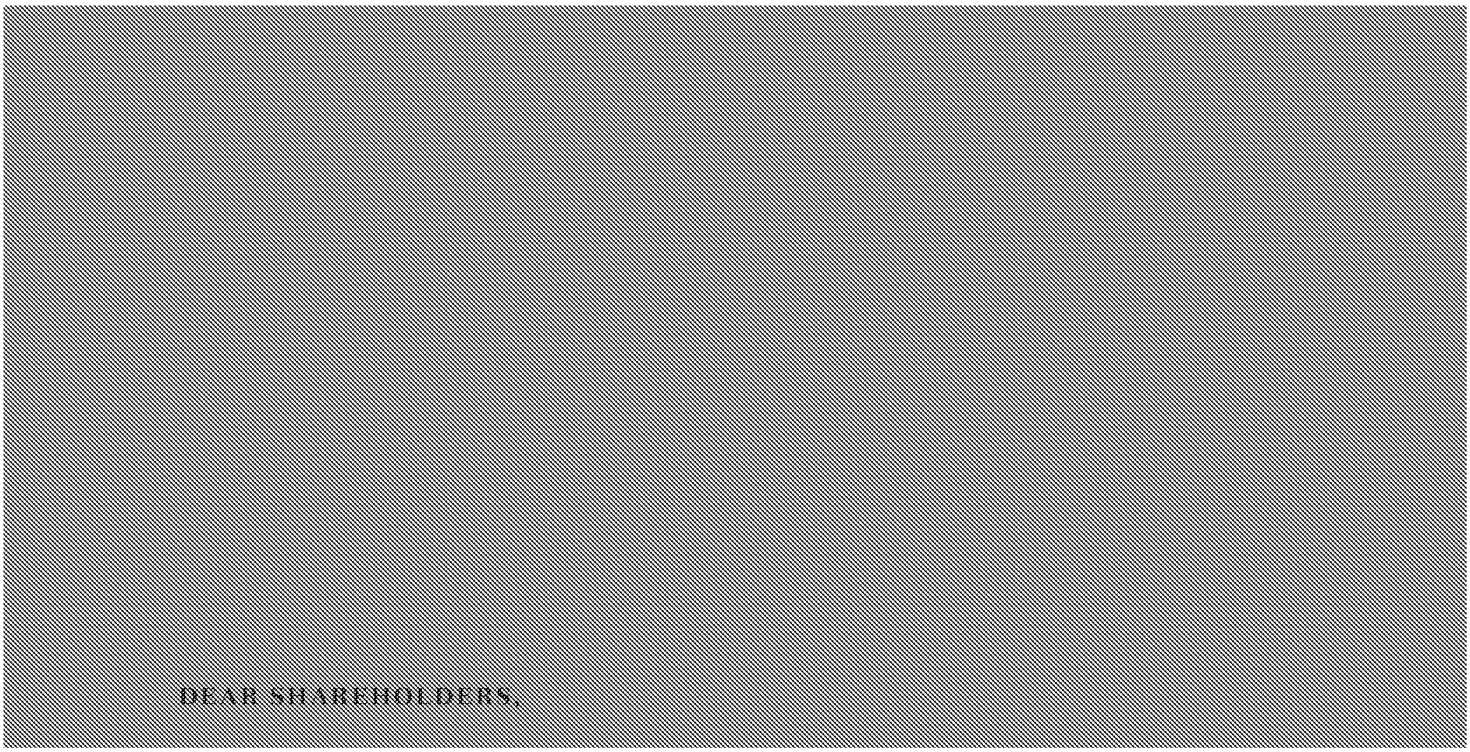


LEONARD S. SCHLEIFER, M.D., PH.D.
President and Chief Executive Officer

P. ROY VAGELOS, M.D.
Chairman of the Board

GEORGE D. YANCOPOULOS, M.D., PH.D.
Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories

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DEAR SHAREHOLDERS,

Reflecting on the past year, one observation stands out: Regeneron is a company that is advancing on all fronts. From discovery through development to manufacturing and commercialization, we have demonstrated our ability to execute our business plan for becoming a fully integrated biopharmaceutical company.

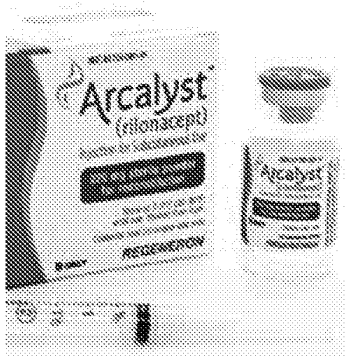
Over the last year:

- We launched our first marketed product, ARCALYST® (rilonacept), an inhibitor of the interleukin-1 cytokine, for Cryopyrin-Associated Periodic Syndromes (CAPS).
- We achieved positive Phase 2 results for rilonacept in drug-induced gout.
- We and sanofi-aventis advanced four Phase 3 studies with aflibercept, our drug candidate targeting Vascular Endothelial Growth Factor (VEGF), in various oncology settings—first-line metastatic hormone-refractory prostate cancer, first-line metastatic pancreatic cancer, second-line non-small cell lung cancer, and second-line metastatic colorectal cancer.
- We and sanofi-aventis started a Phase 2 study of aflibercept in first-line metastatic colorectal cancer.
- We and Bayer HealthCare continued to enroll patients in two Phase 3 studies with VEGF Trap-Eye in wet Age-related Macular Degeneration.
- We and Bayer HealthCare initiated a Phase 2 study of VEGF Trap-Eye in Diabetic Macular Edema.
- We and sanofi-aventis have three *VelocImmune*® antibody product candidates in clinical development and have advanced additional antibodies into preclinical development.
- We greatly expanded our R&D, clinical, and manufacturing capacities.
- We retired our debt and ended 2008 with $527 million in cash and securities.

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1 Approved Product

With FDA approval of ARCALYST™ (rilonacept) as the first and only approved product for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), patients with these rare, hereditary, inflammatory conditions can now live their daily lives with fewer debilitating symptoms.



With the launch of ARCALYST, Regeneron now has the commercial infrastructure and capabilities in place that can be expanded to commercialize larger product opportunities in the United States.

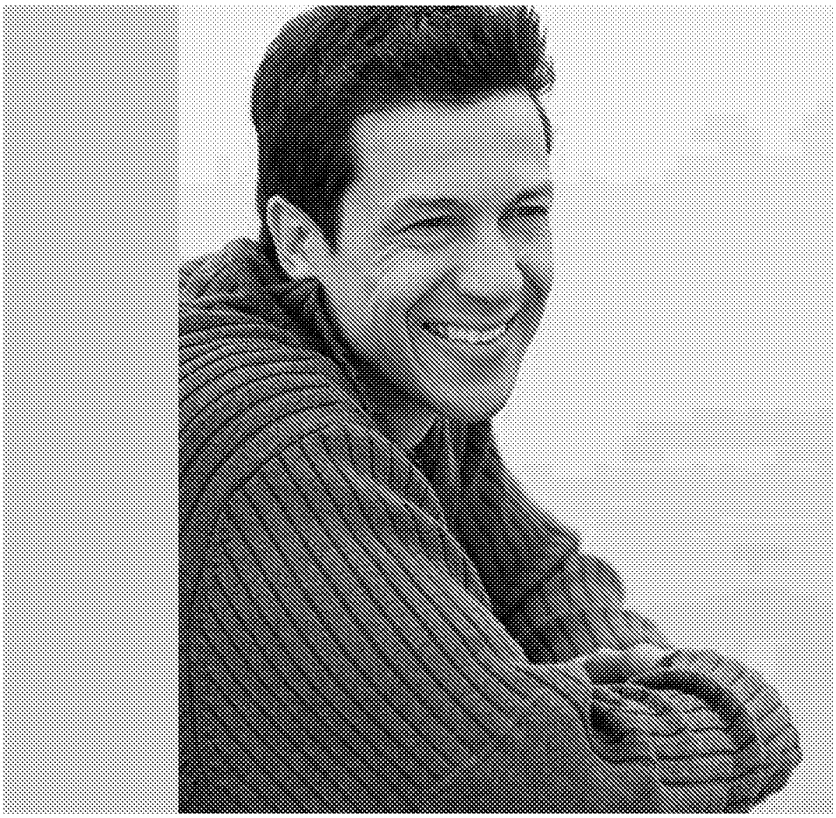
$11 million in ARCALYST shipments in 2008

FROM DISCOVERY THROUGH COMMERCIALIZATION.

In February 2008, the U.S. Food and Drug Administration (FDA) granted marketing approval for ARCALYST 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. This was a watershed event for two important reasons. First, it brings needed relief to CAPS patients who have had no other approved treatment for their debilitating medical condition. During 2008, we transitioned patients who participated in the CAPS pivotal studies from clinical study drug to commercial supplies and shipped approximately **$11 million** of product. Second, FDA clearance demonstrates Regeneron's ability to discover a molecule and take it through clinical development and manufacturing, regulatory review, and commercialization. With the approval of ARCALYST, we can move forward with greater confidence in our ability not only to discover and develop new medicines, but also to manage the process through commercialization.

In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of rilonacept in preventing gout flares induced by the initiation of urate-lowering drug therapy, which is commonly used to control gout. In this 83-patient, double-blind, placebo-controlled study, over the first 12 weeks of urate-lowering therapy, the mean number of gout flares per patient in the rilonacept treatment

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6 Investigational drugs in clinical development

We have drug candidates in all stages of clinical development that target a diverse set of serious conditions, including cancer, eye diseases, inflammatory diseases, and pain.

group was 81 percent lower than in the placebo group. Only 14.6 percent of patients treated with rilonacept experienced a gout flare compared to 45.2 percent of patients treated with placebo. No drug-related serious adverse events were reported in patients receiving rilonacept; injection-site reaction was the most commonly reported adverse event.

We are now enrolling patients in our Phase 3 rilonacept gout program which will include two studies in the prevention of gout flares in patients initiating urate-lowering therapy, one Phase 3 study evaluating rilonacept in the treatment of acute gout flares, and a separate safety study. Regeneron retains worldwide marketing rights to rilonacept.

In gout, uric acid crystals stimulate the production of interleukin-1, which causes an inflammatory response in the joints and surrounding tissues. An estimated one percent of the U.S. population suffers from gout, one of the most painful rheumatic diseases, and 1.4 million people are treated for acute gout attacks each year.

Beyond ARCALYST® (rilonacept), our development pipeline continues to expand and progress. Today we have **6** investigational drugs in clinical development, including three in Phase 3 trials.

VEGF TRAP-EYE.
Our VEGF Trap-Eye program showed strong progress during 2008. In September 2008, we and Bayer HealthCare announced the final one-year data from a Phase 2 study evaluating

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Regeneron currently has Phase 3 clinical trials underway targeting eye disease, various cancers, and gout. In Phase 3 clinical trials, new treatments are compared to either currently available therapies or placebo to assess effectiveness and safety.

Phase 3 Trials Underway

VEGF Trap-Eye in patients with the neovascular form of Age-related Macular Degeneration (wet AMD). Patients receiving VEGF Trap-Eye experienced improvements in vision and retinal thickness (an anatomic measure of treatment effect) during the 12 weeks of fixed monthly or quarterly dosing. These improvements were generally maintained over the next 40 weeks during which patients received VEGF Trap-Eye on a PRN (as needed) dosing schedule. During the PRN dosing period, patients received, on average, only two additional injections. There were no reported drug-related serious adverse events. The most common adverse events were those typically associated with intravitreal injections.

Currently, we and Bayer HealthCare are enrolling two Phase 3 studies of VEGF Trap-Eye in patients with wet AMD. These trials, involving 1200 patients each, are comparing treatment with VEGF Trap-Eye and Genentech's Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. In 2008, we also initiated a Phase 2 study of VEGF Trap-Eye in patients with Diabetic Macular Edema (DME). Initial data from these studies are expected in 2010. Under our collaboration agreement, Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales. We maintain exclusive rights to VEGF Trap-Eye in the United States.

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3 New antibodies in the clinic from the *VelociSuite*™ of technologies

Regeneron's *VelociSuite* of technologies is further accelerating the development of new product candidates. *VelociGene*® and *VelociMouse*® are designed to aid in the identification of specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. *VelocImmune*® increases the speed and efficiency of fully human monoclonal antibody development and is being used to generate antibodies to address clinically relevant targets of therapeutic interest.



AFLIBERCEPT IN ONCOLOGY.
In collaboration with sanofi-aventis, we have underway four Phase 3 studies of aflibercept (VEGF Trap) in combination with chemotherapy that are targeted to enroll a total of approximately 4000 patients. These studies are being conducted in first-line metastatic pancreatic cancer, first-line metastatic hormone-refractory prostate cancer, second-line non-small cell lung cancer, and second-line metastatic colorectal cancer. All studies are approximately 50 percent enrolled, and we expect initial data from three of the studies in 2010. In addition, a Phase 2 combination study of aflibercept in first-line metastatic colorectal cancer began in the first quarter of 2009.

We are also completing a Phase 2 study of single-agent aflibercept in patients with symptomatic malignant ascites, a condition where fluid accumulates in the abdominal cavity in women with advanced ovarian cancer. We expect initial data later this year.

With a total of **9** Phase 3 clinical trials underway or planned, Regeneron has made great strides in advancing the development of our clinical candidates. The progress we've recorded in our gout, eye, and cancer programs, along with the launch of our first marketed product, add up to a very positive year for our company. But they tell only a part of the Regeneron story. Building on our rich tradition of pioneering research, we have developed a suite of technologies for discovering, developing, and manufacturing fully human monoclonal antibodies. We are using this *VelociSuite* of technologies to generate our future pipeline of drug candidates. In fact, it would not be an overstatement to say that we are building a robust antibody development company within Regeneron, with **3** antibodies already in clinical development.

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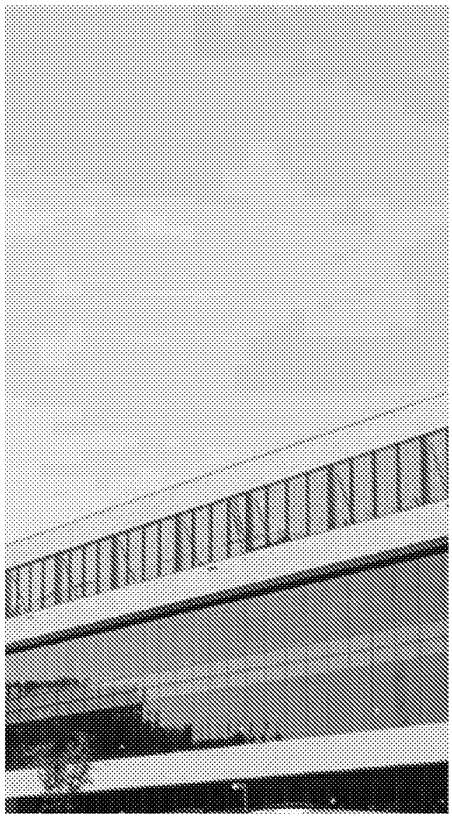


$527 million
in cash and securities at year-end 2008

Regeneron's cash reserves provide significant operating flexibility as we continue to advance our drug candidates through the development pipeline.

Including the funding from our collaboration agreements, our research and development programs are budgeted for over $500 million in spending in 2009. This leveraged spending has enabled us to build a world-class R&D capability.

Over $500 million
in 2009 budgeted R&D spending

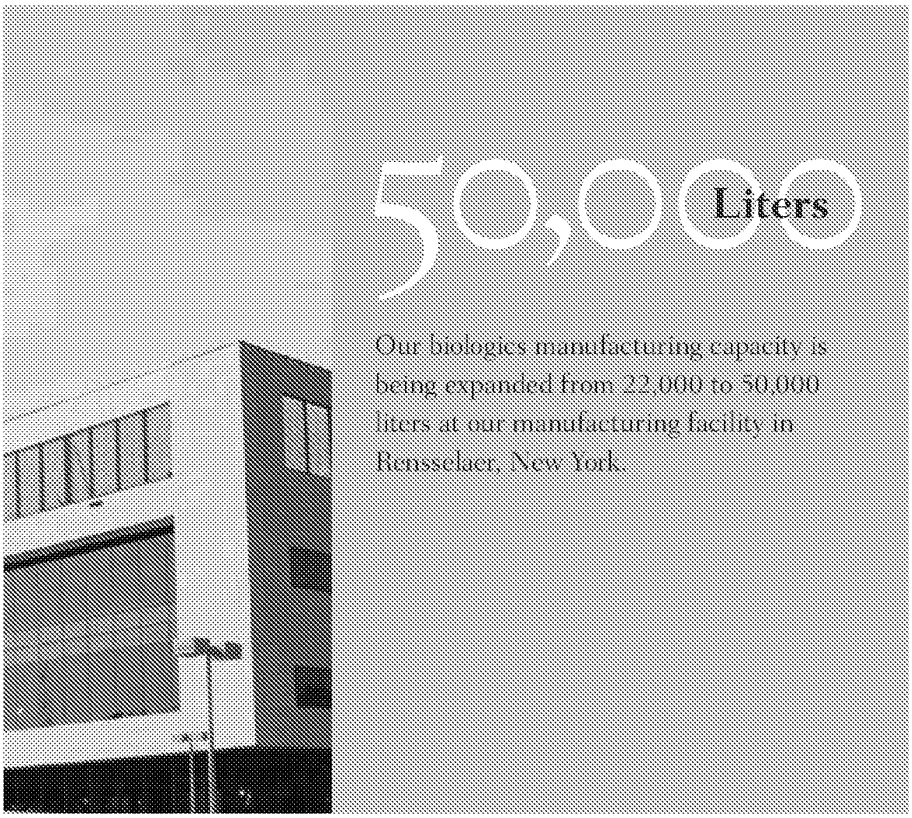


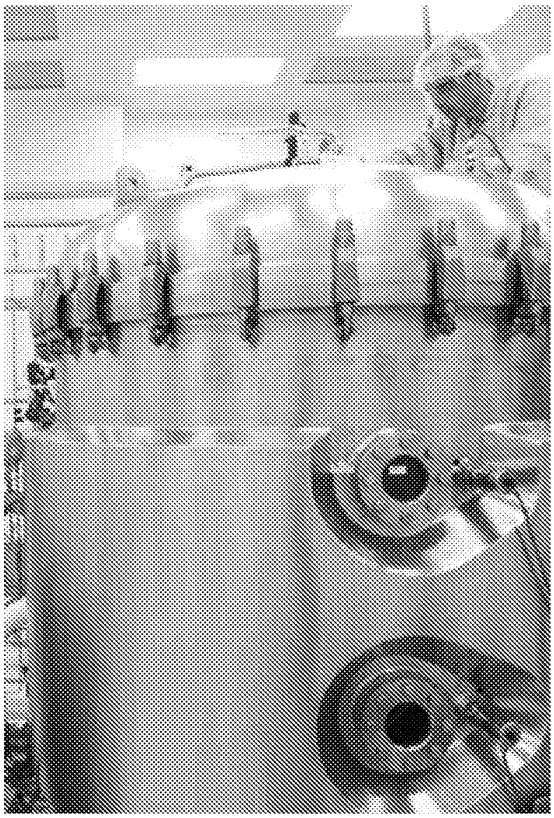
MONOCLONAL ANTIBODY PROGRAM.
Our *VelociSuite*™ of technologies, including *VelocImmune*®, represents a unique platform for identifying and validating novel drug targets and for generating and manufacturing fully human monoclonal antibodies against these targets. In late 2007, we announced a major collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The sanofi-aventis collaboration provides us with up to $100 million in research funding annually through 2012.

Three human antibodies developed under the sanofi-aventis collaboration are in clinical development: REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis; REGN421, an antibody to delta-like ligand-4 (Dll4) that is in development to disrupt angiogenesis in patients with cancer; and REGN475, an antibody against nerve growth factor (NGF) that is in development for the treatment of pain. We are on track with our goal to advance an average of two to three new antibodies into clinical development each year.

In September 2008, we also launched our Academic *VelocImmune* Investigators Program (Academic VIP) when we entered into an agreement to provide researchers at Columbia University Medical Center with access to the *VelocImmune* technology platform. In March 2009, we entered into a similar Academic VIP agreement with The University of Texas Southwestern Medical Center at Dallas. Under the agreements, scientists at the universities

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will use *VelocImmune®* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. Regeneron has an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products. We see opportunities to enter into similar arrangements with other academic institutions.

FINANCIAL STRENGTH.
Clearly, there is a great deal of positive momentum at Regeneron, and we expect 2009 to be no less productive. Fortunately, we have the resources necessary to continue to move forward at this pace. Financially, we are well positioned. We finished 2008 with **$527 million** of cash and securities and no debt. What's more, our ongoing R&D spending will be largely funded by our collaborators. These collaborations are a strong vote of confidence in the promise of our discovery and development capabilities. They also provide significant investment leverage, enabling us to support an R&D program that we expect will exceed **$500 million** in 2009, including spending by sanofi-aventis and Bayer HealthCare.

We are expanding and enhancing our physical footprint to accommodate this level of activity. Later this year, we expect to move into two new buildings totaling 230,000 square feet at our existing Tarrytown, New York site. We are more than doubling our biologics manufacturing capacity to **50,000 liters** at our Rensselaer, New York facility. These are important investments in the future of our company.

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1000 Employees

We increased staff by 35 percent in 2008, primarily to expand our antibody discovery and development capabilities and to advance our clinical-stage product candidates. Now nearly 1000 strong, the highly-motivated Regeneron team is committed to the company's mission.

OUR PEOPLE.

But our most vital investment will always be in our people. During 2008, we launched a major recruiting effort designed primarily to support the antibody collaboration with sanofi-aventis. Our growing reputation in the medical and research communities has enabled us to attract top talent. By year-end 2009, we expect to grow to more than **1000 employees,** up from 682 at the end of 2007, and 919 at year-end 2008.

We will look to this talented group of professionals to continue the momentum we've achieved in the recent past. Last year's accomplishments moved us closer to our goal of having the pipeline, the discovery platform, the financing, and the people needed to bring breakthrough treatments to patients—and to building a world-class biopharmaceutical company for our shareholders.

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During 2008 we asked our employees what it is like to work at Regeneron. From their responses, we drafted and are now featuring in our employee recruiting program these five core attributes of our culture.

The Regeneron

Science drives our business and passion drives our science.

We believe great science leads to new and innovative drugs, which can improve people's lives, grow our company, and fund more great science.

We are a select team.

Regeneron has very high standards for hiring people. If you are talented enough to work here, then you join a team of dedicated people from all walks of life who work together to achieve our goals. Individual effort is rewarded, but true success only comes when we work together as a team.

You will be challenged. Every day.

No matter your role here, you will be expected to strive for excellence in your field. You will never stop learning and you will continually be sharing your knowledge with others.

"That's the way we've always done it" is the wrong answer.

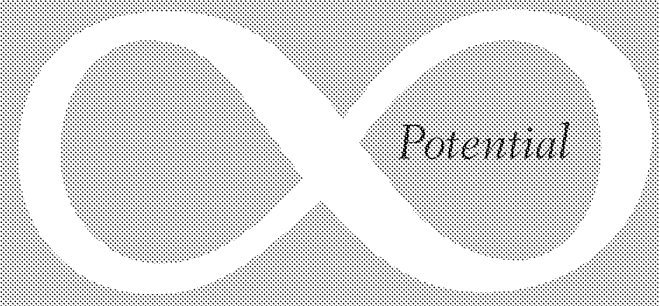
We will not settle for the way things have always been done. At Regeneron, we are willing to see the world in our own way, and we're always looking for new and better ways to do things.

We won't let bureaucracy block good ideas.

Successful companies require organization and processes to function effectively. We have them too, but we work hard to ensure that unnecessary bureaucracy does not stand in the way of conducting great science and developing successful drugs.

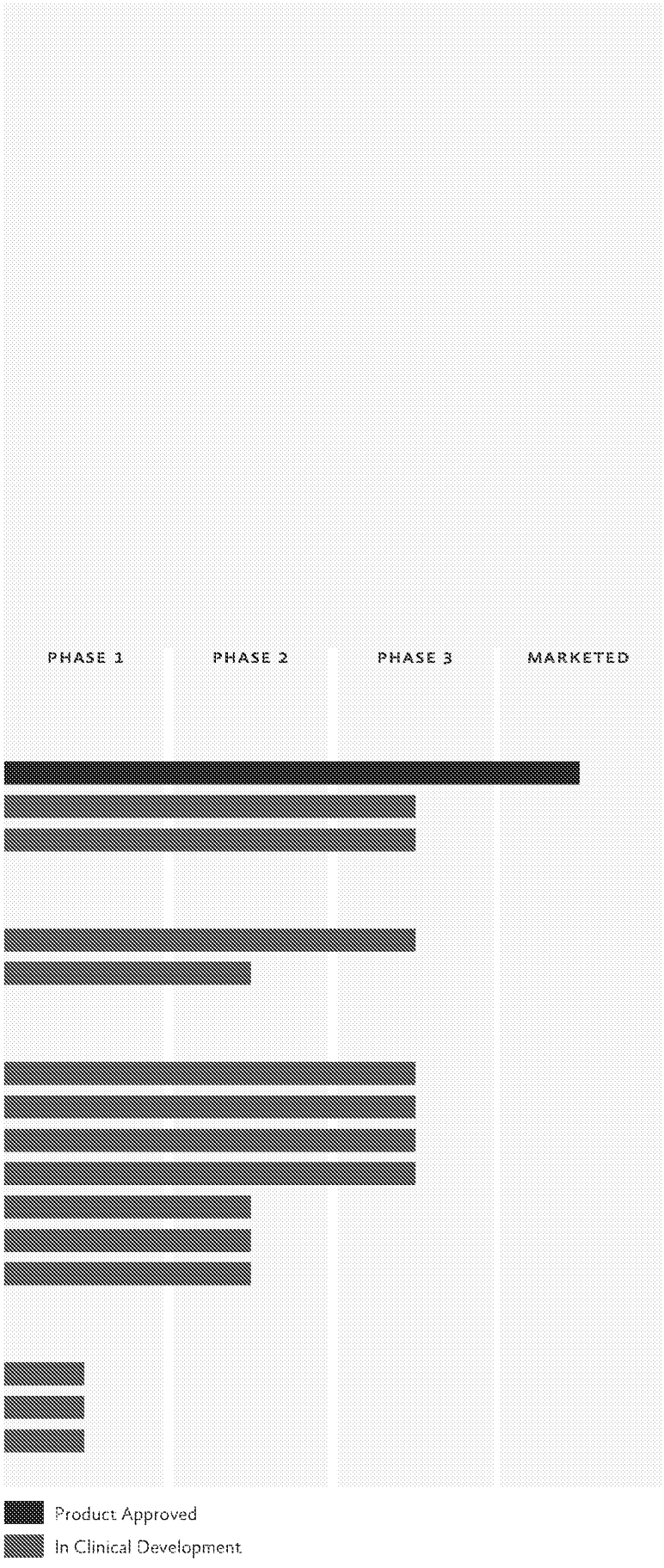
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13 Clinical Programs



With drug candidates in all stages of clinical development, Regeneron has the expertise, infrastructure, resources, and corporate collaborations needed to move these candidates through the development process.

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CORPORATE INFORMATION

COMMON STOCK AND RELATED MATTERS

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market.

2007	HIGH	LOW
First Quarter	$22.84	$17.87
Second Quarter	28.74	17.55
Third Quarter	21.78	13.55
Fourth Quarter	24.90	16.77
2008		
First Quarter	$25.25	$15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62

As of April 14, 2009, there were 476 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock. The closing bid price for the Common Stock on that date was $13.26.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

CORPORATE OFFICE

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SEC FORM 10-K

A copy of our annual report to the Securities and Exchange Commission on Form 10-K is available without charge from the Regeneron Investor Relations Department.

ANNUAL MEETING

The Annual Meeting will be held on Friday, June 12, 2009 at 10:30 a.m. at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, NY 10591.

SHAREHOLDERS' INQUIRIES

Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent, American Stock Transfer & Trust Co., 59 Maiden Lane, Plaza Level, New York, NY 10038, (800) 937-5449. General information regarding the Company, recent press releases, and SEC filings are available on our web site at www.regeneron.com, or can be obtained by contacting our Investor Relations Department at (914) 345-7741.

TRANSFER AGENT AND REGISTRAR

American Stock Transfer & Trust Co.
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New York, NY 10038

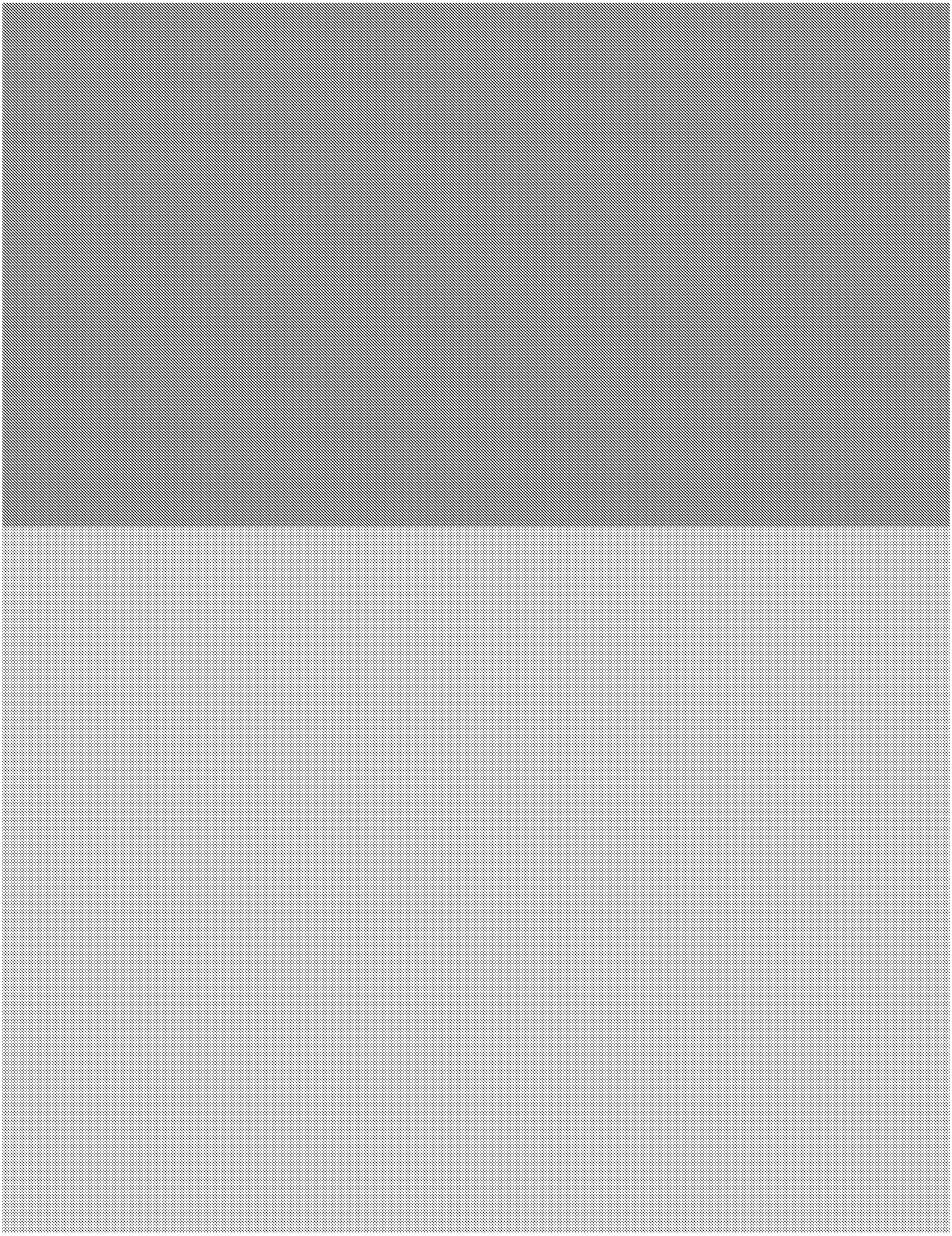
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Financial Information



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Chapter 36
Clincal Development of VEGF Trap

John S. Rudge, Ella Ioffe, Jingtai Cao, Nick Papadopoulos, Gavin Thurston, Stanley J. Wiegand, and George D. Yancopoulos

Keywords: VEGF Trap, vascular eye disease, kinase inhibitors

Abstract: The inhibition of angiogenesis is proving to be an effective strategy in treating diseases involving pathological angiogenesis such as cancer and ocular vascular diseases. Since its discovery in the 1980s, vascular endothelial cell growth factor (VEGF) has been shown to play a vital role in both physiological and pathological angiogenesis, resulting in the development of numerous approaches to block VEGF and VEGF signaling, ranging from small molecule tyrosine kinase inhibitors to protein-based and RNA-based therapeutic candidates. VEGF Trap is one such protein-based agent that has been engineered to bind and sequester VEGF, as well as placental growth factor (PlGF), with high affinity. VEGF Trap has been shown to effectively inhibit pathological angiogenesis in numerous preclinical models of cancer and eye disease, and is now being evaluated in clinical trials in several types of cancer, as well as the 'wet' or neovascular form of age-related macular degeneration (AMD). This chapter will summarize the basic biology of VEGF and the progress of the VEGF Trap from the bench to the clinic.

Introduction

Angiogenesis is a vital process not only during development, but also in the adult in settings of wound repair and reproduction [1, 2]. However, in diseases characterized by uncontrolled, pathological angiogenesis, such as solid tumors or vascular diseases of the eye, inhibition of angiogenesis would be of therapeutic benefit. While diverse factors might be expected to regulate angiogenesis in different settings, a clear consensus is emerging that a single growth factor, VEGF is the critical requisite driver of both physiological and pathological angiogenesis in most settings [3]. Thus, while blocking VEGF signaling during early development can lead to severe growth retardation, it can also produce highly beneficial effects when applied to disease states characterized by pathological neovascularization [3]. Recent clinical studies have validated VEGF as a bona fide target for therapeutic intervention in cancer as well as in vascular diseases affecting the eye, such as wet AMD. These studies have led to approval by the U.S. Food and Drug Administration (FDA) of drugs that target the VEGF pathway, specifically antibodies directed against VEGF, or kinase inhibitors which block activation of the VEGF receptors [4–7]. Emerging therapeutic candidates that otherwise target VEGF signaling have also reported encouraging results [8].

Biology of VEGF and Its Receptors

VEGF is widely known to promote angiogenesis, by stimulating vascular endothelial cell proliferation, migration and tube formation, and it can also markedly increase vascular permeability [9]. VEGF-A is the prototypical member of a family of factors that also consists of VEGF-B, VEGF-C, VEGF-D and PlGF, which bind differentially to VEGF receptors 1, 2 and 3 and neuropilin with different specificities [10,11]. In addition, alternative exon splicing results in the production of four major isoforms of human VEGF-A – $VEGF_{121}$, $VEGF_{165}$, $VEGF_{189}$, $VEGF_{206}$ differentiated by their heparin binding affinity [12]. $VEGF_{121}$ differs from the other isoforms in that it does not bind heparin and thus is freely diffusible. As the isoforms increase in molecular weight, they show increasing heparin binding affinity and consequently bind extracellular matrix such that they tend to be sequestered near their site of production [13–15]. Matrix metalloproteases (MMPs) appear to play an important role in regulating the release of these isoforms from matrix [16]. Although endothelial cells are the primary targets of VEGF actions, more recently it has been shown that other cell types, including monocytes, hematopoietic stem cells and neurons, can also respond to VEGF [17–19].

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The VEGF receptor 2 (VEGFR2) appears to be the major mediator of the mitogenic, angiogenic and pro-permeability actions of VEGF-A. Indeed, genetic deletion of VEGFR2 results in profound defects in embryonic vasculogenesis, including a failure to develop blood islands and organized blood vessels [20]. In contrast, the role of VEGFR1, which was the first VEGF receptor identified, is more difficult to discern [21]. To date, VEGFR1 has been implicated in MMP9 induction, hematopoiesis, and monocyte chemotaxis, and also appears to act as a 'biological sink' which sequesters VEGF from binding to the lower affinity receptor, VEGFR2 [11]. A further level of complexity was revealed when VEGF was shown to bind neuropilin, a molecule previously identified as a receptor for the collapsin/semaphorin family of ligands involved in axon guidance. The binding of VEGF to neuropilin is thought to result in presentation of VEGF to VEGFR2, augmenting VEGFR2 signal transduction [22].

The Evidence for VEGF as a Key Player in Tumor Angiogenesis

In situ hybridization studies have revealed that VEGF is highly expressed in a number of human tumors [23–27]. This is most apparent in renal cell carcinoma where mutations in the von Hippel-Lindau (VHL) tumor suppressor gene result in increased transcription of hypoxia-inducible factor (HIF1) genes [28,29].

Numerous preclinical studies have shown that the growth of many different tumor types can be inhibited using agents that variously inhibit VEGF signaling (small molecule inhibitors, VEGFR2 antibodies, soluble VEGF receptors including the VEGF Trap) [30–35]. These studies have also shown that VEGF derived from the stromal compartment, as well as the tumor itself, plays an important role in mediating the angiogenesis which supports tumor growth [32,36].

Not surprisingly, antiangiogenic therapy results in a cytostatic effect in many tumor types rather than frank regression. Thus, in many models, combination of VEGF blockade with chemotherapy or radiation therapy results in greater efficacy than either approach alone [37,38].

VEGF Pathway Inhibitors Approved for the Treatment of Cancer

Bevacizumab (Avastin®)

The positive results from preclinical studies have led to the testing of several VEGF inhibitors in clinical trials. These include the humanized anti-VEGF-A monoclonal antibody (bevacizumab, Avastin®), an anti-VEGFR antibody [39], small molecules that inhibit VEGFR signaling and VEGF Trap [4,40–42]. The first clinical validation of the anti-VEGF approach came with FDA approval of bevacizumab in 2004, based on the results of a randomized double-blind phase III trial in which bevacizumab was combined with bolus IFL (irinotecan, 5FU, leucovorin) chemotherapy as first line therapy for metatstatic colorectal cancer. Median survival increased from 15.6 months in the IFL alone arm to 20.3 months in the IFL + bevacizumab arm. Severe hypertension was observed in about 10% of bevacizumab treated patients, and gastrointestinal perforation was noted in ~2% of patients. In addition, the incidence of arterial thromboembolic complications (stroke, myocardial infarction, transient ischemic attacks, unstable angina) was double the incidence seen with chemotherapy alone [43].

Kinase Inhibitors

An alternative approach to using antibodies that bind and neutralize VEGF is the use of tyrosine kinase inhibitors that target the VEGF and other receptors. To date, two such kinase inhibitors have been approved by the FDA: SU11248 (sunitinib; Sutent®) and Bay 43–9006 (sorafenib; Nexavar®). Sunitinib inhibits tyrosine phosphorylation of VEGFR1, VEGFR2, platelet derived growth factor receptor (PDGFR), c-kit and Flt3, and has been approved for the treatment of Gleevec-resistant gastrointestinal stromal tumors (GIST) and metastatic renal cell carcinoma [7]. Sorafenib, which inhibits tyrosine phosphorylation of raf, VEGFR2/3, PDGFR, kit and Flt3, was approved in 2006 for the treatment of metastatic renal cell carcinoma [5,6]. It should be pointed out that these kinase inhibitors do not block VEGF signaling selectively or completely, and much of their clinical benefit could derive from the inhibition of other kinase pathways.

Development and Application of VEGF Trap in Preclinical Animal Models

Despite the important benefits in patient care provided by the currently approved VEGF pathway blockers, current evidence suggests that optimal VEGF blockade may not have yet been achieved (e.g., dose response studies do not indicate that saturation of benefit has been reached) [44,45], raising the possibility that more potent VEGF blockade could provide even more benefit for patients. The VEGF Trap may provide the opportunity to test this hypothesis, as it was designed to bind VEGF with exceedingly high-affinity. The VEGF Trap is a soluble chimeric receptor in which key domains of VEGFR1 (domain 2) and VEGFR2 (domain 3) are fused to the constant region (Fc portion) of human IgG1 [34]. This fully human protein is capable of binding all isoforms of VEGF-A with very high affinity (KD <0.5 pM for $hVEGF_{165}$). Moreover, and in contrast to antibodies directed against VEGF-A, the VEGF Trap also binds PlGF, a VEGF family member also implicated in pathological angiogenesis [46] (KD ~25 pM for hPlGF2). In addition, the VEGF Trap was engineered to exhibit excellent pharmacokinetic properties, and has a circulating half-life in humans of approximately 2–3 weeks, allowing for bi-weekly or even less frequent dosing.

Once VEGF Trap had been optimized, it was tested and shown to have significant antiangiogenic and anti-tumor efficacy in

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numerous preclinical tumor models [34,37,38,47–50]. When administered in combination with chemotherapy or radiation, VEGF Trap also produced a significant additive impact on tumor growth. Moreover, in an ovarian cancer model, VEGF Trap potently inhibited ascites formation [37,38,50]. The impressive efficacy profile of VEGF Trap in preclinical animal models justified its progression into clinical trials.

Interestingly, VEGF Trap also has an additional property that distinguishes it from antibodies: while antibodies form multimeric complexes with their antigens that are rapidly cleared from the systemic circulation, VEGF Trap forms an inert 1:1 complex with VEGF that remains in the circulation and can thus be readily measured. Thus, when given in doses that saturate VEGF binding, this unique property of the VEGF:VEGF Trap complex allows for the accurate determination of tumor and whole body VEGF production rates [51]. Somewhat surprisingly, when non-tumor bearing animals and humans are given the VEGF Trap, we find that total body production rates of VEGF are quite high, challenging previous claims that systemic VEGF levels can be used as a sensitive measure of tumor burden [51]. This finding has the important corollary that agents designed to bind and inactivate tumor-derived VEGF must be provided in amounts sufficient to ensure that they are not effectively consumed by the large amounts of VEGF normally produced by the body. Building on this finding, we have determined that measurement of the levels of free and bound VEGF Trap provides a clear index of the doses required to capture all available VEGF, offering a useful guide for dosing of this antiangiogenic agent. Based on these assays, the doses currently being used in the clinic for cancer appear to be in the therapeutic range.

VEGF Trap in Clinical Trials for Cancer

Multiple Phase 1 trials have been carried out using the VEGF Trap as a single agent, or in combination with various chemotherapeutic regimens, in patients with advanced cancers, with more than 300 patients treated to date. Numerous objective responses as well as cases of prolonged stable disease have been noted in these trials. Interestingly, in addition to anti-tumor responses, improvements in tumor-associated co-morbidities have been observed: in particular, substantial or complete resolution of tumor-associated ascites. The major adverse events noted in these trials are consistent with those seen with other anti-VEGF agents, and include hypertension and proteinuria. Importantly, no antibodies to VEGF Trap were observed in any patients.

VEGF Trap is currently in Phase II clinical trials and is about to initiate multiple large Phase 3 trials. Preliminary results from two of these studies were recently reported at the American Society of Clinical Oncology 2007 annual meeting [41,42] Results were reported from an interim analysis of a randomized, double-blind, multi-center Phase 2 trial comparing two doses of VEGF Trap in patients with recurrent, platinum-resistant epithelial ovarian cancer. The patients selected for this study were heavily pre-treated and had failed several other treatment regimens. While the study remains blinded with respect to dose, the pooled preliminary results from both the high and low dose groups demonstrated anti-tumor activity, as evidenced by an 8% objective tumor response rate, with a 13% response rate as measured by a 50% reduction in circulating levels of the tumor marker CA-125. Disease was judged to be stable in 77% of patients at 4 weeks, and in 41% of patients at 14 weeks. In addition, of 24 patients in the study who had tumor-associated ascites, 29% experienced complete resolution of their ascites while 54% experienced no increase in ascites during treatment. Tolerability was similar to other molecules in this class with hypertension being the most common grade 3/4 event (16%). Two patients (1.2%) experienced bowel perforation, both of whom recovered. In a collaboration involving Sanofi-Aventis and Regeneron Pharmaceuticals, the ongoing single-agent studies of VEGF Trap will be complemented by a large Phase 3 program combining VEGF Trap with standard chemotherapy regimens in at least 5 different advanced solid tumors: colorectal, non-small cell lung, prostate, pancreas and gastric cancer, with the first of these studies initiating in 2007.

Preclinical Studies with VEGF Trap in Vascular Eye Diseases

The finding that VEGF-A was up-regulated in the aqueous and vitreous humor of patients with proliferative diabetic retinopathy extended the focus of antiangiogenic agents from cancer to vascular eye disease [52,53]. Wet age-related macular degeneration (AMD) is the most common cause of vision loss in the elderly [53,54]. In this disease, VEGF is believed to mediate the abnormal growth of choroidal vessels that, together with the associated vascular leak and edema, disrupts the normal retinal architecture. VEGF Trap has also been tested in a number of rodent models of ocular vascular disease, where it has been shown to inhibit choroidal [55] and corneal [56] neovascularization in addition to suppressing vascular leak in the retina [57]. VEGF Trap has also been shown to improve the survival of corneal transplants [58]. In a primate model of AMD, in which a laser was used to induce choroidal vascular lesions, intravitreal administration of VEGF Trap was found not only to prevent the development of vascular leak and neovascularization when administered before the time of injury but also completely resolved vascular leak when administration was delayed until after the lesions had fully developed [59].

VEGF Trap in Clinical Trials for Vascular Eye Disease

The promising results in preclinical models supported the introduction of VEGF Trap into the clinic for treatment of both wet AMD and diabetic macular edema, using a version of VEGF Trap specifically formulated for intra-ocular administration,

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termed VEGF Trap-Eye. Following successful completion of Phase I studies in wet AMD, VEGF Trap-Eye has progressed to a Phase 2 trial, for which interim results were recently presented at the Association for Research in Vision and Ophthalmology (ARVO) 2007 annual meeting [60,61]. In this trial, VEGF Trap-Eye was given at monthly intervals at doses of 0.5 or 2.0 mg, or as a single injection of 0.5, 2.0 or 4.0 mg. In the interim analysis, VEGF Trap-Eye met the pre-specified primary endpoint of reducing retinal thickness as measured by ocular coherence tomography (OCT) at 12 weeks compared with baseline (all groups combined, decrease of 135 μm, $P < 0.0001$). Mean change in visual acuity, a key secondary endpoint of the study, also demonstrated a statistically significant improvement (all groups combined, increase of 5.9 letters, $P < 0.0001$). Interestingly, patients in the highest monthly dose group achieved an average vision gain of more than 10 letters at 12 weeks, and even a single injection of VEGF Trap-Eye resulted in improved mean visual acuity at 12 weeks (all dose levels combined). Thus, the increased potency of VEGF Trap-Eye may offer the potential for improved efficacy and/or longer dosing intervals compared to the current standard of care [62–64]. In the VEGF Trap-Eye Phase 2 trial, there were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. A Phase III program for VEGF Trap-Eye in wet AMD will be initiated in 2007.

In addition, as reported at ARVO 2007 [60,65], a Phase 1 study of VEGF Trap-Eye in diabetic macular edema (DME) showed that a single intravitreal injection in patients with longstanding diabetes resulted in a marked decrease in mean central retinal thickness and mean macular volume throughout the 6 week observation period. Additional trials with VEGF Trap-Eye in DME are anticipated in the future.

Conclusion

The VEGF Trap is an all human, chimeric receptor-based protein engineered to potently bind all forms of VEGF-A and PIGF, and to exhibit superior pharmacokinetic properties. The promise of the VEGF Trap in preclinical models of cancer and vascular eye diseases is being maintained during its initial evaluation in Phase 1 and 2 human trials, offering the hope that this therapeutic candidate may offer additional benefit to patients suffering from cancer or blinding vascular eye diseases.

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ARVO Annual Meeting Abstract | April 2011

Primary Results of an International Phase III Study Using Intravitreal VEGF Trap-Eye Compared to Ranibizumab in Patients with Wet AMD (VIEW 2)

Ursula Schmidt-Erfurth; Victor Chong; Bernd Kirchhof; Jean-Francois Korobelnik; András Papp; Majid Anderesi; Georg Groetzbach; Bernd Sommerauer; Rupert Sandbrink; Yuichiro Ogura

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2011, Vol.52, 1650. doi:

Abstract

Purpose: : To evaluate efficacy and safety of different dose and interval regimens of VEGF Trap-Eye (VTE) vs monthly ranibizumab in patients with choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD) at 12 months in a international setting.

Methods: : A total of 1240 patients from Europe, Latin America, Asia, and Australia were randomized to VTE 0.5 mg monthly (4 weeks; 0.5q4wk), 2 mg monthly (2q4wk), 2 mg every two months (8 weeks; 2q8wk) following 3 monthly doses, or ranibizumab 0.5 mg monthly (Rq4wk). The primary endpoint was the proportion of patients maintaining vision (loss <15 ETDRS letters) from baseline to week 52. Secondary endpoints included mean change in best corrected visual acuity (BCVA) at Week 52. Central retinal thickness was assessed monthly.

Results: : There were 72.4% Caucasian and 21.6% Asian patients included. The proportions of patients maintaining vision at week 52 were 94.4%, 96.3%, 95.6%, and 95.6% for Rq4wk, 0.5q4wk, 2q4wk, and 2q8wk, respectively. All VTE arms were non-inferior to ranibizumab. Mean improvements in BCVA for Rq4wk, 0.5q4wk, 2q4wk and 2q8wk were 9.4, 9.7, 7.6, and 8.9 letters; differences between the VTE arms and Rq4wk were non-significant. The incidences of ocular treatment emergent adverse events (AEs) were similar across all treatments, with the most frequent AEs associated with the injection procedure, the

underlying disease, and/or the aging process. Conjunctival hemorrhage, macular degeneration, retinal hemorrhage, and reduced visual acuity were the most frequent ocular AEs. There were no concerns regarding systemic safety in any arm.

Conclusions: : Across different ethnicities, VEGF Trap-Eye monthly or every two months was non-inferior to monthly treatment with ranibizumab with a favorable safety profile. Based on the study data, the new management paradigm in wet AMD with treatment every two months using VEGF Trap-Eye can be recommended regardless of the ethnicity.

Clinical Trial: : http://www.clinicaltrials.gov NCT00637377

Keywords: age-related macular degeneration • vascular endothelial growth factor

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ARVO Annual Meeting Abstract | April 2010

Influence of Baseline Angiographic Classification on Outcomes in the CLEAR-IT 2 Phase 2 Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration

J. S. Slakter; CLEAR-IT 2 Study Group

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2010, Vol.51, 2055. doi:

Abstract

Purpose: : To determine if treatment outcomes for patients enrolled in the CLEAR-IT 2 study of VEGF Trap-Eye in patients with neovascular AMD were influenced by baseline fluorescein angiographic characteristics, including the presence of cystoid macular edema (CME), retinal angiomatous proliferation (RAP), and serous pigment epithelial detachments (PEDs).

Methods: : CLEAR-IT 2 was a randomized, multicenter, prospective dose and dose-interval ranging study designed to assess the safety and efficacy of VEGF Trap-Eye in patients with subfoveal choroidal neovascularization secondary to AMD. Patients with neovascular AMD (n=157) received VEGF Trap-Eye 0.5 or 2.0 mg monthly or 0.5, 2.0, or 4.0 mg quarterly for 12 weeks, followed by PRN dosing to 1 year. Anatomic efficacy measures were assessed using optical coherence tomography (OCT) and fluorescein angiography (FA). All OCT and FA images were assessed by central reading centers. A subanalyis was performed for patients who entered the study with CME (n=12), RAP lesions (n=7), and serous PED (n=10).

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Results: : For all groups combined (n=157), mean change in visual acuity from baseline at 1 year was 5.3 letters (p<0.0001) with 63 of the 157 patients (40%) gaining 2 or more lines. The mean change in central retinal/lesion thickness from baseline was -130µm (p< 0.0001) at 1 year. For patients with RAP lesions at baseline, mean change in visual acuity at week 52 was + 6.3 letters, with 4 of the 7 patients gaining 2 or more lines. For patients with CME at baseline, mean change in visual acuity at week 52 was +12 letters with 8 of the 12 patients gaining 2 or more lines. For patients with serous PED at baseline, mean change in visual acuity at week 52 was +6.7 letters, with 5 of the 10 patients gaining 3 or more lines.

Conclusions: : VEGF Trap-Eye produced significant improvements in visual acuity in patients with CME, RAP lesions, and serous PEDs similar to those seen with the overall patient population.

Clinical Trial: : www.clinicaltrials.gov NCT00320788

Keywords: age-related macular degeneration • choroid: neovascularization • vascular endothelial growth factor

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ARVO Annual Meeting Abstract | April 2009

A Phase 2, Randomized, Controlled Dose- and Interval-Ranging Study of Intravitreal VEGF Trap-Eye in Patients With Neovascular Age-Related Macular Degeneration: Optical Coherence Tomography (OCT) and Fluorescein Angiography (FA) Outcomes at 1 Year

J. S. Slakter; CLEAR-IT 2 Investigators

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2009, Vol.50, 1890. doi:

Abstract

Purpose: : To present 1 year data on VEGF Trap-Eye, a fusion protein that penetrates all retinal layers binding with high affinity to all VEGF-A isoforms and placental growth factor, with special emphasis on anatomic outcomes as measured by optical coherence tomography (OCT) and fluorescein angiography (FA).

Methods: : In this randomized, double masked, multi-center Phase 2 trial, patients with neovascular AMD received VEGF Trap-Eye 0.5 or 2.0 mg monthly or 0.5, 2.0, or 4.0 mg quarterly for 12 weeks, followed by PRN dosing to 1 year. Anatomic efficacy measures included changes from baseline in central retinal/lesion thickness (CR/LT), total macular volume (TMV), and pigment epithelial defect thickness (PED) as measured by OCT, and total lesion area and choroidal neovascularization (CNV) area as determined by FA. All OCT and FA images were assessed by central reading centers.

Results: : One year results for all groups combined (n=157) demonstrated significant decreases from baseline in CR/LT of -130µm ($p< 0.0001$), in TMV of -1.1 mm^3 ($p< 0.0001$) and in PED thickness (n = 46 with PED at baseline) of -102µm. All groups combined at 1

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year showed a modest decrease from baseline in total lesion size (mean change of -0.39 mm^2), and significant reductions of active CNV size (mean change of -2.21 mm^2, $p< 0.0001$) and classic CNV size (mean change of -1.21 mm^2, $p< 0.0001$). Patients dosed with 2 mg monthly for 12 weeks followed by PRN dosing, in general, achieved the largest improvements in anatomic as well as visual acuity measures.

Conclusions: : VEGF Trap-Eye produced significant reductions in CR/LT, TMV and PED thickness as well as significant reductions in CNV and classic CNV size at 1 year compared to baseline.

Clinical Trial: : www.clinicaltrials.gov NCT00320788

Keywords: age-related macular degeneration • choroid: neovascularization • vascular endothelial growth factor

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Electronic Acknowledgement Receipt

EFS ID:	40026640
Application Number:	16397267
International Application Number:	
Confirmation Number:	8135
Title of Invention:	USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS
First Named Inventor/Applicant Name:	George D. YANCOPOULOS
Customer Number:	96387
Filer:	Karl Bozicevic/Kimberly Zuehlke
Filer Authorized By:	Karl Bozicevic
Attorney Docket Number:	REGN-008CIPCON5
Receipt Date:	16-JUL-2020
Filing Date:	29-APR-2019
Time Stamp:	18:49:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	57_20110503_REGENERON_PHARMACEUTICALS_INC_8-K_5_3.pdf	264229 106fb3f1a49444514a48ba37aa2eaf95873b6f04	no	13

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National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

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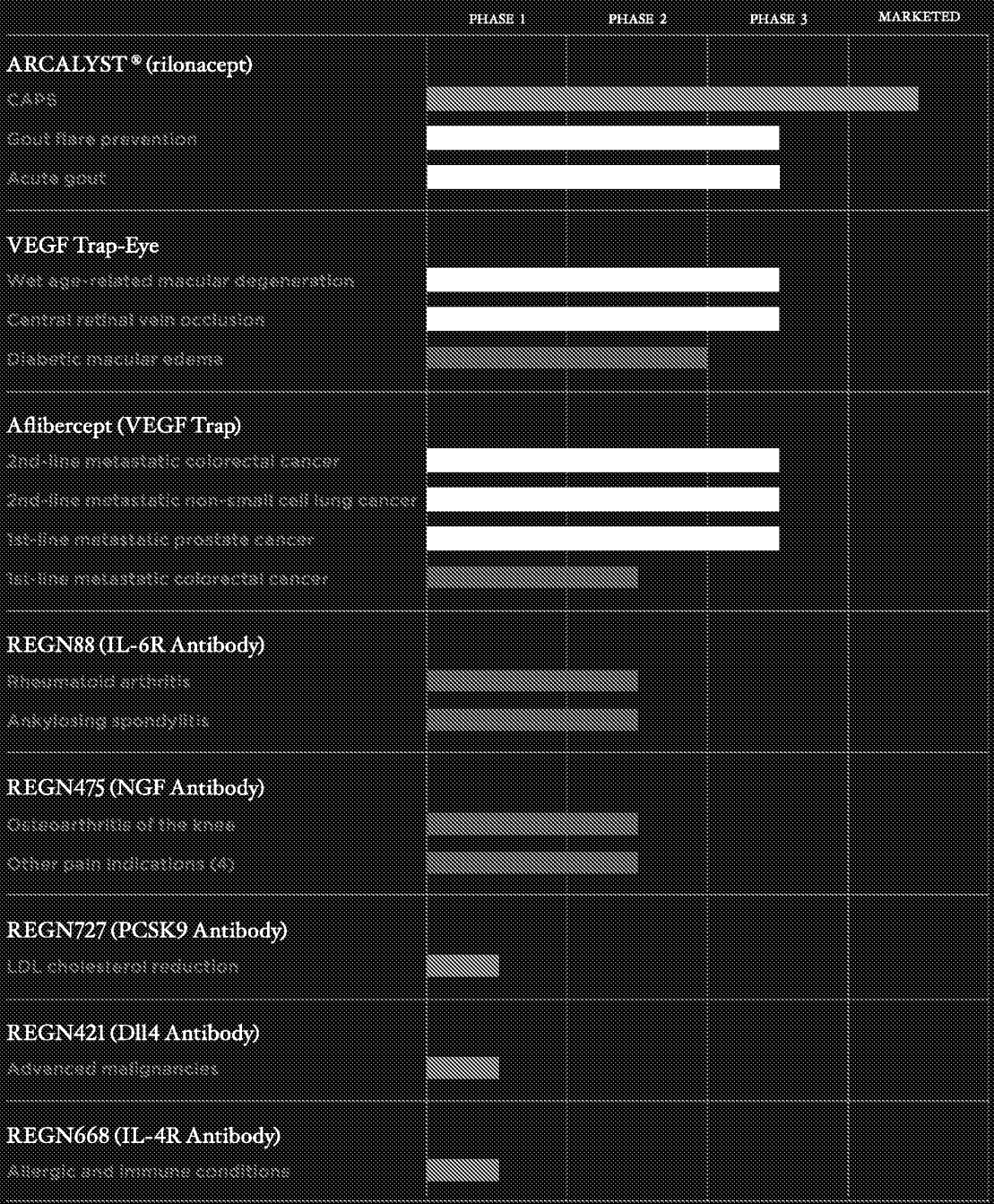
annual report 2009

science drives our business

REGENERON

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Clinical programs



and passion drives our science

Regeneron is at one of the most exciting moments in its history. We've selected the messages and images in the opening section of this Annual Report to evoke who we are and what we do as we strive to bring innovative new medicines to patients in need.

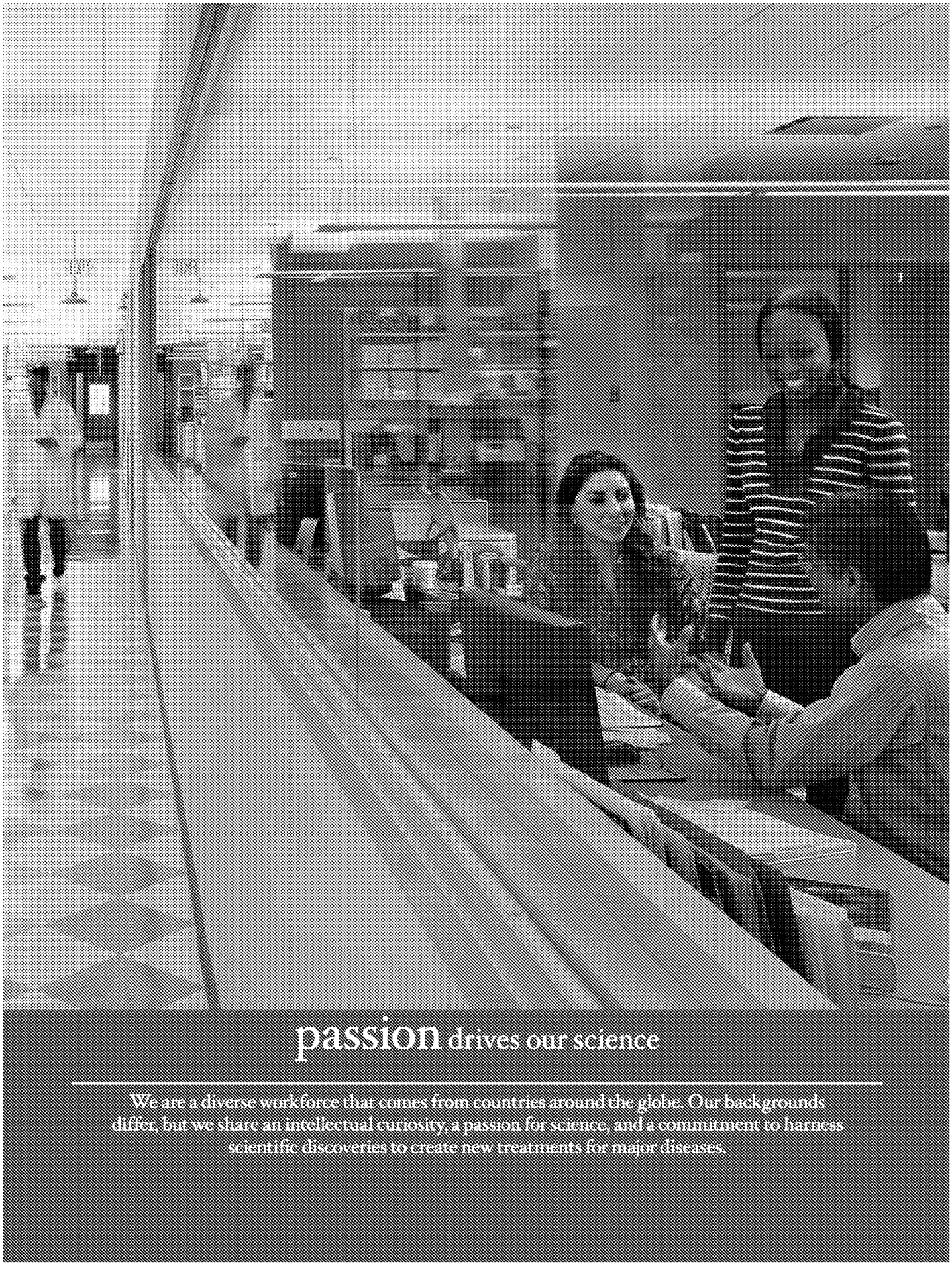
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science drives our business

Innovative science was and remains the foundation of our company. Discovery is our lifeblood. All our drug candidates come from our own laboratories, based on proprietary technologies that we developed for creating fully human monoclonal antibodies and fusion proteins we call Traps.

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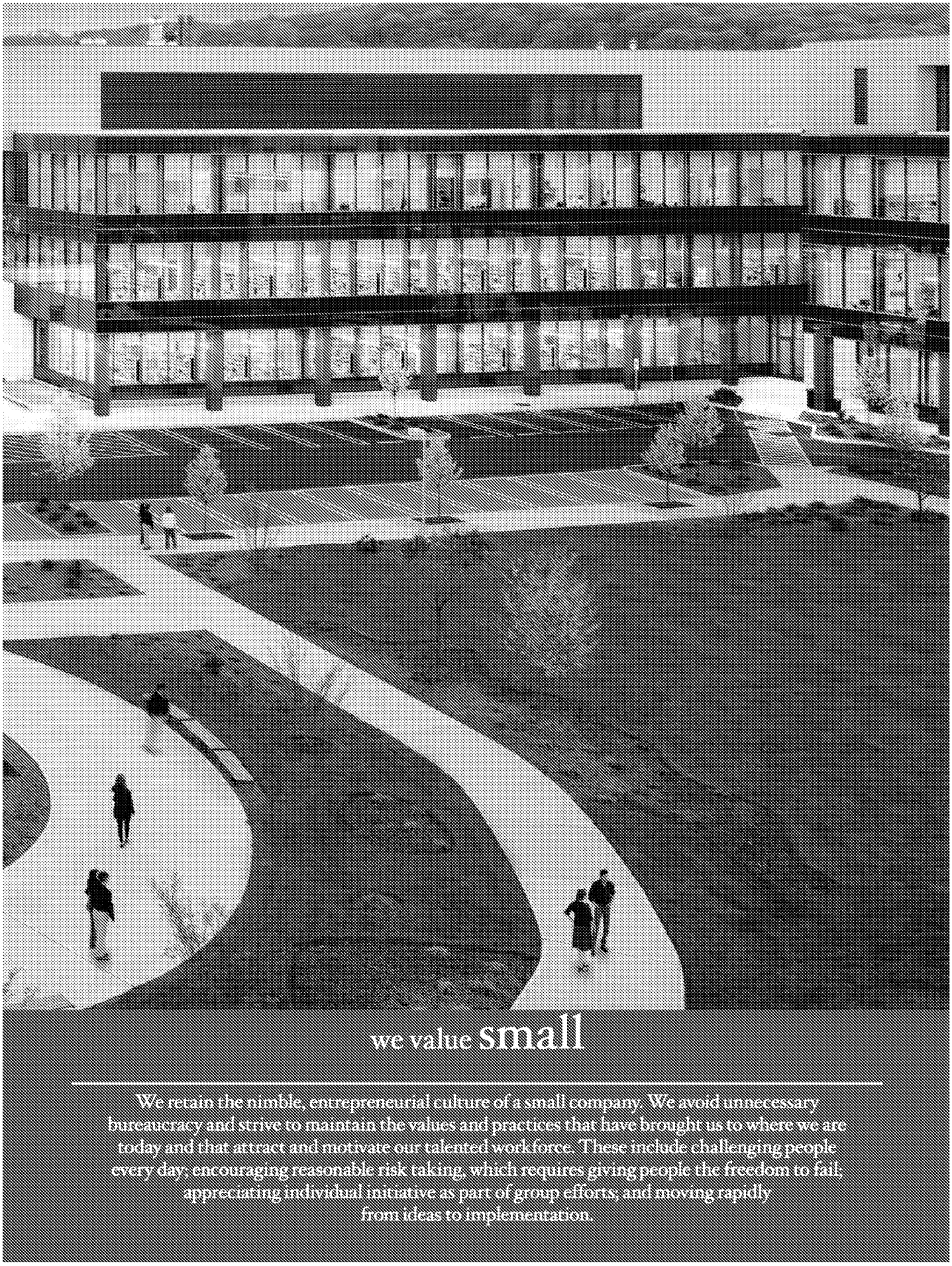
passion drives our science

We are a diverse workforce that comes from countries around the globe. Our backgrounds differ, but we share an intellectual curiosity, a passion for science, and a commitment to harness scientific discoveries to create new treatments for major diseases.



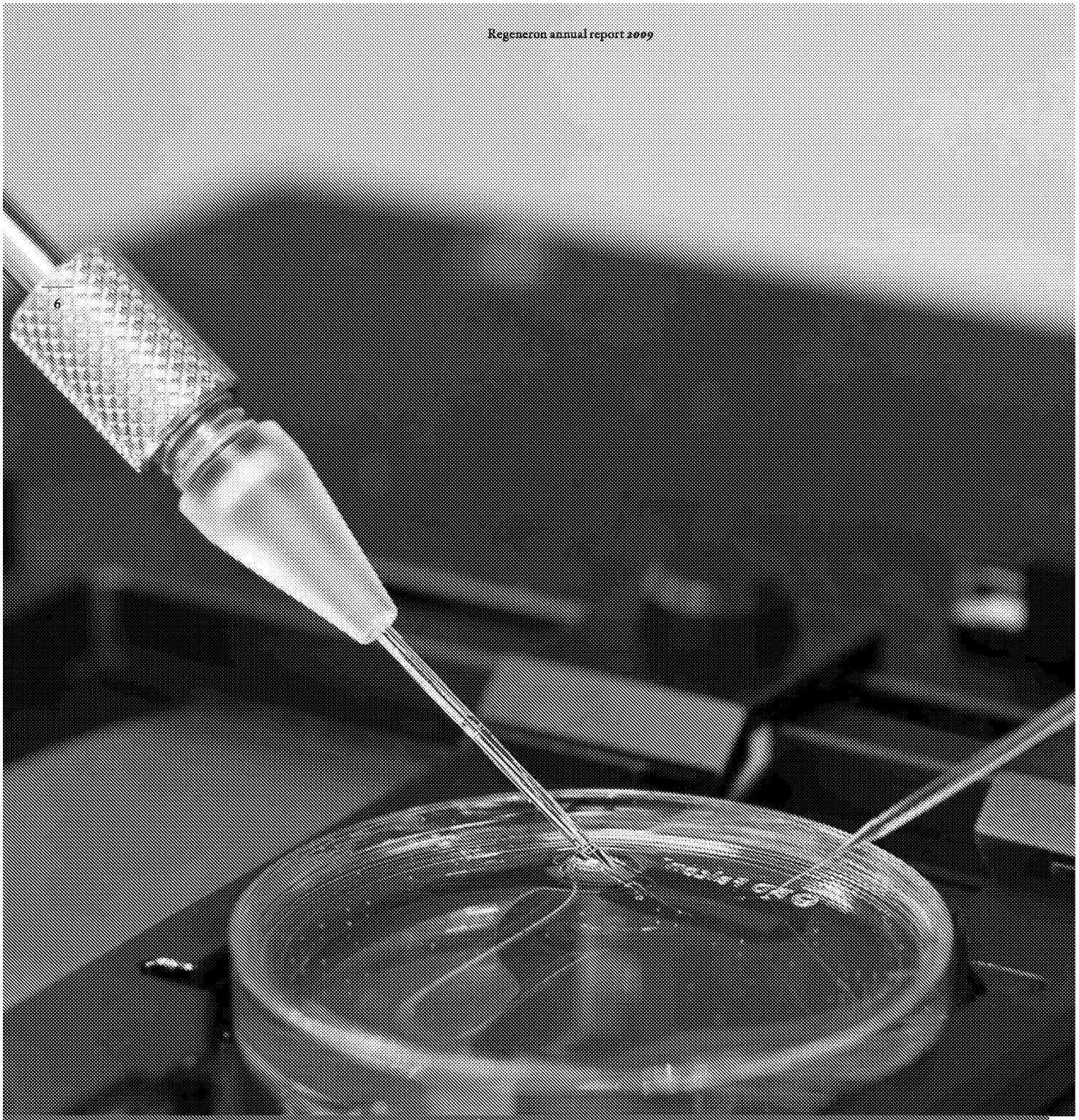
we are becoming big

We operate on a large scale. We have eight product candidates in clinical development for 19 different indications. Our research and development spending, including expenditures by our collaborators on partnered programs, topped $570 million in 2009 and should exceed $700 million in 2010. To support our growing pipeline, we employ over 1,000 people and expect to add about another 500 employees by year-end.



we value small

We retain the nimble, entrepreneurial culture of a small company. We avoid unnecessary bureaucracy and strive to maintain the values and practices that have brought us to where we are today and that attract and motivate our talented workforce. These include challenging people every day; encouraging reasonable risk taking, which requires giving people the freedom to fail; appreciating individual initiative as part of group efforts; and moving rapidly from ideas to implementation.



we discover

We make discoveries by challenging ourselves to see science and medicine differently. Ever since we opened our doors in 1988, our commitment has been to conduct the best science to make new discoveries that lead us forward. For example, after creating a proprietary gene manipulation technology, VelociGene®, to study the function of genes, we developed our VelocImmune® technology to make fully human monoclonal antibodies suitable as drug candidates.

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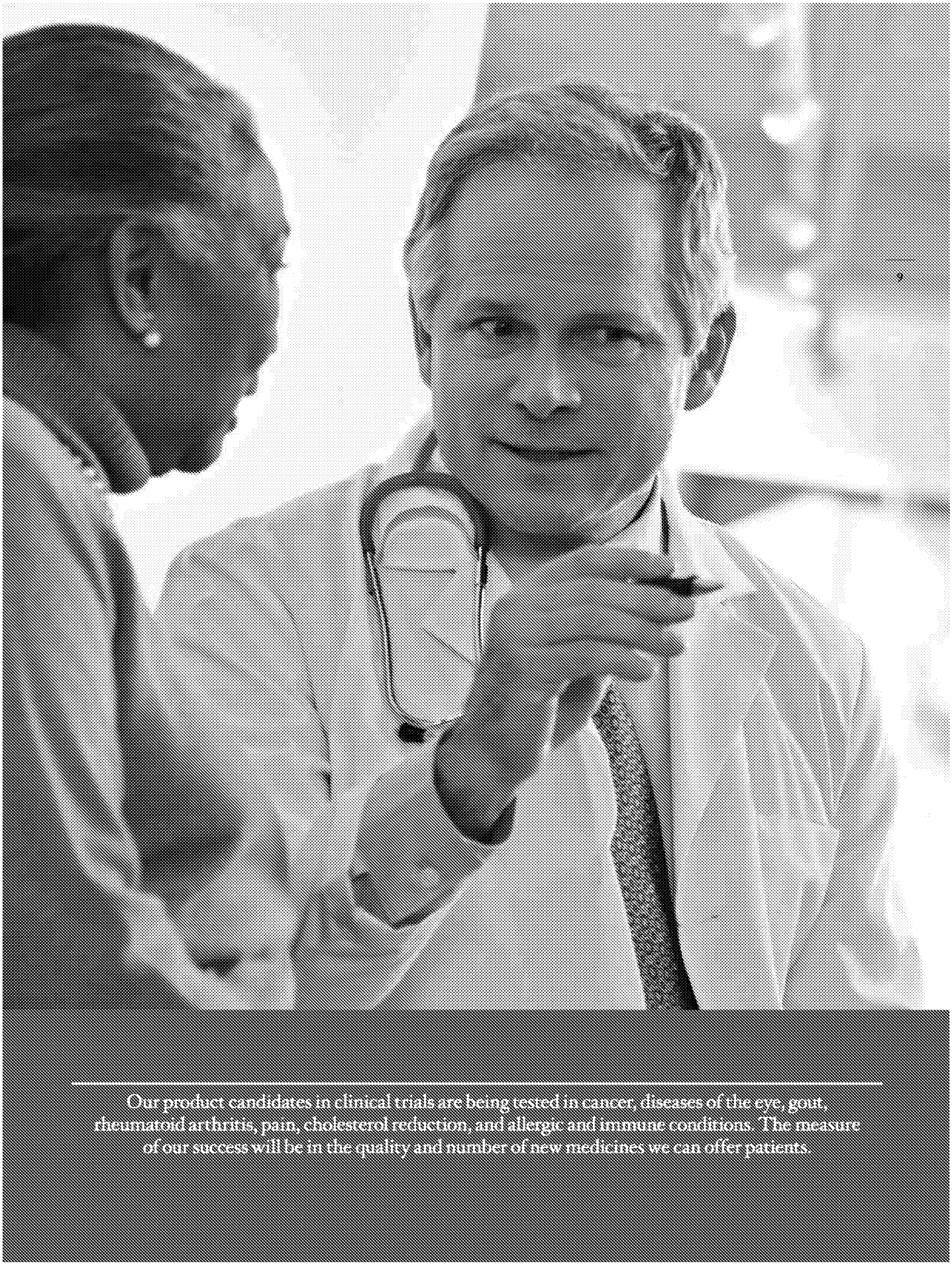
and develop

We have the full range of development capabilities, from conducting preclinical research to running large-scale clinical trials. With our collaborators, sanofi-aventis and Bayer HealthCare, we are managing clinical trials globally. We manufacture our approved product and all of our product candidates at our industrial operations facility in Rensselaer, New York, following process development in our protein science labs in Tarrytown, New York.



we're here to help patients

Our ultimate goal is to bring new drugs to market that make a difference in the lives of patients. In 2008, ARCALYST® (rilonacept) Injection for Subcutaneous Use became our first marketed product and the first drug approved in the United States for the treatment of a rare genetic disease.



Our product candidates in clinical trials are being tested in cancer, diseases of the eye, gout, rheumatoid arthritis, pain, cholesterol reduction, and allergic and immune conditions. The measure of our success will be in the quality and number of new medicines we can offer patients.

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*D*ear shareholders,

During 2009, we made significant advances in our clinical programs as well as with our discovery research and preclinical development initiatives. We also expanded our antibody collaboration with sanofi-aventis to provide even greater resources to utilize our VelocImmune® human monoclonal antibody technology to grow our clinical pipeline substantially over the next eight-to-ten years. In our research labs, production facilities, and offices, there is palpable excitement about 2010 – a year that promises to be one of the most pivotal in Regeneron's history as we ramp up our expanded antibody discovery efforts and await Phase 3 clinical trial results in multiple programs.

As this annual report goes to press, 11 Phase 3 clinical studies are underway with three molecules created from our Trap fusion protein technology. These studies span a variety of diseases with unmet medical needs, including gout (four studies of our interleukin-1 inhibitor, rilonacept), retinal diseases (four studies of VEGF Trap-Eye for use in intraocular applications, in collaboration with Bayer HealthCare), and cancer (three studies of our Vascular Endothelial Growth Factor inhibitor, aflibercept [VEGF Trap], in collaboration with sanofi-aventis).

We also expect to report study results this year in multiple antibody programs partnered with sanofi-aventis. Today, most external attention is focused on our current Phase 3 programs. Soon, antibodies like REGN88 (anti-Interleukin-6 Receptor) for rheumatoid arthritis, REGN475 (anti-Nerve Growth Factor) for pain, and REGN727 (anti-PCSK9) to lower LDL cholesterol may take their place alongside our Phase 3 compounds as significant value drivers for Regeneron shareholders.

A Transformative Collaboration

The agreement to expand and extend our 2007 antibody collaboration with sanofi-aventis to discover, develop, and commercialize fully human therapeutic monoclonal antibodies promises to be truly transformative for Regeneron and ranks as one of the larger Big Pharma-biotech collaborations in the history of the biotechnology industry. Sanofi-aventis increased its annual commitment to fund discovery and preclinical research at Regeneron from $100 million to up to $160 million. This funding, originally scheduled to expire after 2012, now will extend through 2017.

As under the original 2007 collaboration terms, sanofi-aventis has an option to codevelop any antibody candidates when they are ready to enter clinical trials, and if sanofi-aventis exercises its option, it will generally pay 100 percent of clinical development costs. This provision of the agreement could generate billions of dollars of development funding for Regeneron

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George D. Yancopoulos, M.D., Ph.D.
Executive Vice President, Chief Scientific Officer, and President, Regeneron Research Laboratories

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

P. Roy Vagelos, M.D.
Chairman of the Board



above and beyond the $1.3 billion in research funding. Once antibody products from the collaboration reach the market, we and sanofi-aventis will split any resulting profits 50/50 in the United States. Outside the United States, profits will be split according to a formula under which our share will range from 35–45 percent. We will repay half of the clinical expenses funded by sanofi-aventis out of our share of the profits, subject to a cap of 10 percent of our share of the profits in any calendar quarter.

With more funding, we plan to bring an average of four to five new antibodies into clinical development each year through 2017, for a total of 30–40 new clinical-stage compounds over this time frame. During the first two years of the collaboration, Regeneron advanced five antibodies into clinical development, achieving the original goal of bringing two to three antibodies into clinical development each year. While few biotechnology companies of any size consistently bring four to five new drug candidates into clinical development each year, our track record over the first two years of the collaboration, coupled with our current robust research programs and preclinical pipeline, gives us confidence that we can meet our goal.

In the long and challenging course of drug development, more drug candidates fail than succeed — this is a fact of life in the pharmaceutical business. If we advance 30–40 high-quality antibody drug candidates into clinical development under the sanofi-aventis collaboration over the next eight years, we will have created a deep pipeline of antibody product candidates. In this way, we believe the expanded antibody collaboration changes the risk-reward profile for Regeneron shareholders. We have secured long-term funding that creates many more opportunities for success, and we have retained a sizeable profit participation in the partnered products.

2009 – A Year of Progress

Now let's review our operational highlights over the last year.

ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS)

- ARCALYST® (rilonacept) Injection for Subcutaneous Use, our first marketed product, had shipments to distributors of $20 million in 2009. During the year, rilonacept was also approved under exceptional circumstances by the European Medicines Agency for use in CAPS.

Rilonacept in gout

- In 2009, we initiated registration-directed trials of rilonacept for the treatment of acute gout and prevention of drug-induced gout flares, following a successful Phase 2 flare prevention study, reported in 2008, in patients who initiated urate-lowering drug therapy. Gout is a painful and often debilitating form of arthritis that affects about three million Americans. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in patients with acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a nonsteroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a 1,200 patient placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy.

  Patient enrollment was completed at the end of 2009 in PRE-SURGE 1 and in February 2010 in SURGE. Initial results in both trials should be available by mid-2010. We expect results from the remaining two gout studies during the first half of 2011.

  Regeneron maintains worldwide exclusive ownership of rilonacept.

VEGF Trap-Eye in eye diseases

- In the fourth quarter of 2009, we and Bayer HealthCare completed enrollment of two Phase 3 studies of VEGF Trap-Eye (VIEW 1 and VIEW 2) in patients with the neovascular form of Age-Related Macular Degeneration (wet AMD). The studies compare VEGF Trap-Eye to Lucentis® (ranibizumab injection, a trademark of Genentech, Inc.), the standard of care in wet AMD. One year data from these studies are expected in late 2010. In addition, during 2009 we initiated two Phase 3 studies (COPERNICUS and GALILEO) in patients with Central Retinal Vein Occlusion (CRVO), with initial data from these studies expected in early 2011.
- In February 2010, we and Bayer HealthCare reported positive clinical results from a randomized, controlled Phase 2 study evaluating VEGF Trap-Eye in patients with clinically significant diabetic macular edema (DME). In each of the four treatment arms, VEGF Trap-Eye achieved the primary study endpoint, a statistically significant improvement in visual acuity over 24 weeks compared to focal laser therapy, the standard of care in DME. VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease.
- We are developing VEGF Trap-Eye in collaboration with Bayer HealthCare. Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where we will share equally in profits from any future sales. We maintain exclusive rights to VEGF Trap-Eye in the United States.

Aflibercept (VEGF Trap) in oncology

- With our collaborator, sanofi-aventis, we are developing VEGF Trap, known as aflibercept, for the potential treatment of solid tumors. Anti-VEGF therapy with other agents has been approved for the treatment of certain cancers. In our

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program, patient enrollment is complete in Phase 3 studies in colorectal, lung and prostate cancer. In these studies, aflibercept is being evaluated in combination with the standard of care chemotherapy treatment. The primary endpoint in each study is overall survival, measured when a prespecified number of deaths have occurred. In the VELOUR study evaluating aflibercept as a second line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan), an interim analysis is expected in the second half of 2010, with final results in the second half of 2011. We currently anticipate completion of the VITAL trial evaluating aflibercept as a second line treatment for non-small cell lung cancer in combination with docetaxel during the first half of 2011. We also anticipate that an interim analysis of the VENICE trial evaluating aflibercept as a first line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone will be conducted during the first half of 2011, with final results available in 2012.

- In June 2009, we reported results of a Phase 2 study of aflibercept in women with advanced ovarian cancer who had recurrent symptomatic malignant ascites (SMA), an abnormal buildup of fluid in the abdominal cavity. Aflibercept was clinically active in this setting and met the primary study endpoint. Nonetheless, after reviewing the study data, we and sanofi-aventis concluded that it was difficult to definitively assess the overall clinical benefit that might be derived from treatment in the real-world clinical practice setting and, therefore, that the data were not sufficient to submit for regulatory approval in the SMA setting.
- Clinical development is not without its challenges. In September 2009, we and sanofi-aventis announced the discontinuation of a Phase 3 clinical trial evaluating aflibercept plus gemcitabine for the first line treatment of metastatic pancreatic cancer after the Independent Data Monitoring Committee for the trial determined that aflibercept would not show meaningful improvement over current therapy.

REGN475 for pain

- This antibody binds to nerve growth factor (NGF), a novel target for pain indications. During 2009, we and sanofi-aventis completed a Phase 1 study and initiated Phase 2 studies in osteoarthritis of the knee and other pain indications. We expect initial Phase 2 results this year. A number of pharmaceutical companies also have anti-NGF product candidates in clinical development.

REGN88 for rheumatoid arthritis

- This antibody binds to the interleukin-6 (IL-6) receptor, blocking its ligand, IL-6. During 2009, we and sanofi-aventis completed several Phase 1 studies. In the first quarter of 2010, we began a Phase 2/3 study in rheumatoid arthritis, for which another IL-6 antibody recently has been approved, and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine.

REGN421 for advanced malignancies

- This antibody binds to Delta-like ligand-4 (Dll4), a novel anti-angiogenesis target. In 2009, we and sanofi-aventis continued to study REGN421 in a Phase 1 study in patients with advanced malignancies.

REGN727 for cholesterol reduction

- This antibody binds to PCSK9, a novel target for LDL cholesterol reduction. We and sanofi-aventis initiated a Phase 1 study during the fourth quarter of 2009.

REGN668 for allergic and immune conditions

- This antibody binds to the interleukin-4 receptor, a target implicated in allergic and immune conditions. We and sanofi-aventis initiated a Phase 1 study during the fourth quarter of 2009.

Industrial Operations

At our manufacturing facilities in Rensselaer, New York, our industrial operations are on track to double our production capacity to 54,000 liters by the end of 2010. Each of our drug candidates in clinical development, as well as our marketed product, ARCALYST® (rilonacept), is manufactured at our Rensselaer site. We believe that our in-house process development and large-scale manufacturing capabilities represent critical competencies for a biopharmaceutical company.

New lab and office space

To accommodate our growth, most employees moved last fall into two new buildings constructed for us on the Tarrytown, New York campus we have occupied since 1989. The state-of-the-art facility (featured in the photography on the preceding pages) makes ample use of glass and natural light to create a feeling of openness and collaboration, sustainable materials such as bamboo flooring, and energy-saving features including heat-reflecting white roofs. A third new building with identical design is under construction next door and is slated for occupancy in 2011.

Recruiting Talent

Clearly, there's a lot of momentum at Regeneron, and our early and late-stage clinical pipeline has never been so full. To meet our ambitious objectives under the sanofi-aventis antibody collaboration, we are recruiting new talent at Regeneron. We employed more than 1,000 people at the start of 2010 and aim to hire approximately 500 more staff by the end of the year, many to support the research, development, and production commitments under our antibody collaboration. Hiring so many scientists, manufacturing personnel, and other staff to support our expanding pipeline will be a challenge, but we are experienced in meeting such challenges: In 2008–09, we increased staff by more than 50 percent to meet the deliverables of the initial antibody collaboration initiated in late 2007, and we have already recruited 185 new employees in the first quarter of 2010.

Meeting our recruitment targets while preserving our science-driven culture is an important goal. With so much going on at the company, and with many Big Pharma and small biotechs reducing staff, we are well positioned to continue to attract top talent. A major advantage in our recruiting is the energy and passion of our people, which are visible to job candidates and other visitors to our operations in Tarrytown and Rensselaer.

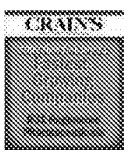
We are pleased that Regeneron has been recognized over the last year with several awards. *The Scientist* selected us for the third year in a row as one of the best places to work for scientists in biotechnology. *Fast Company* cited us one of the most innovative companies in the world. *Forbes.com* named us among its 100 most trust worthy companies that have "consistently demonstrated transparent and conservative accounting practices and solid corporate governance and management." These and other recognitions are featured below.

We were recognized over the last year for the following achievements:













Our Financial Position Is Strong, Too

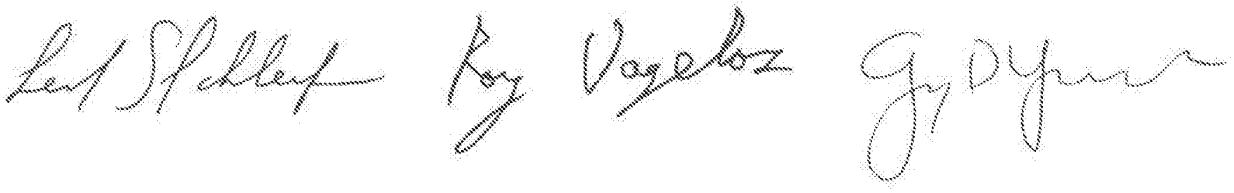
In 2009, our revenues were $379 million compared to $238 million in 2008. In both years, a majority of revenues were reimbursements from sanofi-aventis and Bayer HealthCare for our spending on collaboration programs. Including R&D expenditures on collaboration programs by sanofi-aventis and Bayer HealthCare, total 2009 R&D spending on our programs was over $570 million, compared to approximately $400 million in 2008.

Our cash usage was $146 million in 2009 compared to $126 million in 2008. These figures exclude proceeds from stock option exercises and, in 2008, repayment of convertible debt. Our relatively modest cash burn in relation to the size of our R&D programs is due to our collaborations with sanofi-aventis and Bayer HealthCare. We refer to the difference between our cash burn and total R&D expenditures as "research leverage." We believe this provides strategic value, as the structure of our collaborations makes it possible to conduct R&D on a scale much greater than we could support on our own. We expect total R&D spending in 2010, including spending by sanofi-aventis and Bayer HealthCare on collaboration programs, to be over $700 million.

Looking Ahead

As we look ahead, we can say that Regeneron entered 2010 from a position of strength. We are fueled by a productive and energized first-class research and development organization that has built a robust clinical pipeline. We have drug candidates in all stages of development, and these address a broad range of therapeutic indications. Strong science and R&D programs are further bolstered by productive collaborations and a healthy balance sheet. Regeneron has no debt (other than lease obligations) and at March 31, 2010 had $414 million in cash and investments.

All of these opportunities would not be possible without the tireless commitment of our employees, our collaborators, and our clinical investigators; the courageous participation of the patients in our clinical studies; and the support from you, our shareholders. We thank you all as we continue to do cutting-edge science and strive to bring better medicines to patients worldwide.



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financial information

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2009

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	13-3444607
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No)*
777 Old Saw Mill River Road, Tarrytown, NewYork	10591-6707
(Address of principal executive offices)	*(Zip code)*

(914) 347-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**Nasdaq Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $1,355,426,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2009, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 12, 2010:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	2,211,698
Common Stock, $.001 par value	79,441,680

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2010 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 65 to 68 of this filing.

PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the commercial success 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.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*™ technology platforms. Our discovery platforms are designed to identify specific 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 five antibody product candidates currently in clinical trials were developed using *VelocImmune*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

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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 $20.0 million of ARCALYST® (rilonacept) to our distributors in 2009, compared to $10.7 million in 2008. We own worldwide rights to ARCALYST.

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. Rilonacept is not currently marketed in the European Union.

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. **Rilonacept – Inflammatory Diseases***

We are evaluating rilonacept in gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of rilonacept versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy. 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 rilonacept (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 rilonacept, 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 rilonacept 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 rilonacept (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 rilonacept, 22.0% experienced a gout flare (p=0.0209 versus placebo) and none had more than one flare. Adverse events after 16 weeks of treatment were similar to those reported after 12 weeks with the most frequently reported categories being infection and musculoskeletal complaints.

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

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During the first quarter of 2009, we initiated a Phase 3 clinical development program with rilonacept for the treatment of gout. The program includes four clinical trials. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy. SURGE and PRE-SURGE 1 are fully enrolled. We expect to report initial data from SURGE and PRE-SURGE 1 during the first half of 2010 and from PRE-SURGE 2 and RE-SURGE during the first half of 2011.

Royalty Agreement with Novartis Pharma AG

In June 2009, we entered into a royalty agreement with Novartis Pharma AG that replaced a previous collaboration and license agreement. Under this agreement, we are entitled to receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1β antibody. We waived our right 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, type 2 diabetes, and a number of other inflammatory diseases.

2. VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare 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 (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in late 2010.

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.

In this Phase 2 study, 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

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week 12 to week 52 in the PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Twenty-four-month results of the extension stage were presented in October 2009 at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters ($p<0.0001$ versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters ($p<0.0001$ versus baseline) at one year, and 6.1 letters ($p<0.0001$ versus baseline) at month 12 of the extension stage. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye dosing regimens versus laser treatment. A total of 240 patients with clinically significant DME with central macular involvement were randomized to five groups. VEGF Trap-Eye achieved the primary endpoint of the study, a statistically significant improvement in visual acuity compared to focal laser therapy, the standard of care in DME. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 ($p< 0.01$ for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. 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

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of the first patient in a Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a $20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in CRVO. We can earn up to $70 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to $135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

3. Aflibercept (VEGF Trap) – Oncology

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

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in three Phase 3 trials that combine aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. VITAL and VENICE are fully enrolled, and the VELOUR study is approximately 95% enrolled. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with FOLFOX (folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin) is approximately 75% enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a prespecified number of events have occurred in each trial. Based on current enrollment and event rates, (i) an interim analysis of VELOUR is expected to be conducted by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

A fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued in September 2009 following a planned interim efficacy analysis by that study's IDMC. 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 in the combination arm with aflibercept were generally as anticipated.

During 2009, summary results were reported for a randomized, placebo-controlled Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA), an abnormal build-up of fluid in the abdominal cavity. Patients receiving aflibercept experienced a statistically significant improvement (55 days with aflibercept as compared to 23 days for patients receiving placebo ($p=0.0019$)) in the primary study endpoint, mean time to first repeat paracentesis (removal of fluid from the abdominal cavity), versus placebo control. There was a statistically similar incidence of deaths in both treatment groups. Four fatal events were assessed by the investigators as aflibercept treatment related. The types and frequencies of adverse events reported with aflibercept in this study were generally consistent with those reported in clinical studies with other anti-VEGF therapies in AOC patients. Although the study demonstrated that aflibercept is a clinically active agent in this setting, given the small number of patients enrolled in this study and their fragile health status, we and sanofi-aventis concluded that it was difficult to definitively assess the overall clinical benefit that might be derived from treatment in the real-world clinical practice setting and, therefore, the data were not sufficient to submit for regulatory approval in the SMA indication.

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Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

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

4. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF generated using our *VelocImmune*® technology. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4/5, or BDNF.

In the third quarter of 2009, we began a Phase 2 double-blind, placebo-controlled, dose-ranging, proof-of-concept study of REGN475 in persons with osteoarthritis of the knee. Preliminary data from that study are expected in the first half of 2010. Additionally, four Phase 2 proof-of-concept studies in other pain indications (sciatica, vertebral fracture, chronic pancreatitis, and thermal injury) were initiated in late 2009 and early 2010. REGN475 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune* technology that is in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune* technology. REGN421 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

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7. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR, which prevents LDLR from binding to LDL and removes it from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune®* technology to derive a fully human monoclonal antibody called REGN727 that is designed to bind to PCSK9 and prevent it from inhibiting LDLR. REGN727 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

8. REGN668 (Anti-IL4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL4Ra) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune* antibody that is designed to bind to IL4R. REGN668 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST® (rilonacept), as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

VelociSuite™

VelociSuite consists of *VelocImmune, VelociGene®, VelociMouse®, and VelociMab™*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the

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opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab™* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to $30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. To date, sanofi-aventis has opted into the development of five antibody candidates. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of $21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

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AstraZeneca U K L imited. 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 annual payment in the first quarter of 2010. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made $20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of $20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the second quarter of 2010. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. 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

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.

Sales and Marketing

We have established a small commercial organization to support sales of ARCALYST® (rilonacept) for the treatment of CAPS in the United States. We have no sales or distribution personnel and distribute the product through third party service providers. We currently have no sales, marketing, commercial, or distribution organization outside the United States. If we receive regulatory approval to market and sell additional products in the United States or in other countries, we may either expand our commercial organization or rely on third party product licensees or service providers.

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. We currently have approximately 27,500 liters of cell culture capacity at these facilities and have plans to increase our manufacturing capacity to approximately 54,000 liters in 2010. Up to $30 million of agreed-upon costs related to this expansion will be funded by sanofi-aventis under the terms of our amended antibody collaboration. At December 31, 2009, we employed 278 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2009.

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Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors – *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.*"). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Eli Lilly and Company, Abbott, sanofi-aventis, Merck & Co., Amgen Inc., Roche, and others. 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. Competition from smaller competitors may also be or become more significant if those competitors acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even when we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST®(rilonacept). In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab (Ilaris®), a fully human anti-interleukin-IL1β antibody, for the treatment of CAPS. Canakinumab is also in development for chronic gout and a number of other inflammatory diseases. In October 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. In addition, there are both small molecules and antibodies in development by other third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Xoma Ltd. are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over ARCALYST. The successful development and/or commercialization of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST.

VEGF Trap-Eye. The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis) for the treatment of wet AMD, DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab). The relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute (NEI) initiated a Phase 3 trial to compare Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. Data from this NEI study are expected to be published in 2011. Avastin (Genentech) is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

Aflibercept (VEGF Trap). Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

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In particular, Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Pfizer, Imclone/Eli Lilly, AstraZeneca, and GlaxoSmithKline. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer and Onyx (together with its partner Bayer Healthcare) are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

Monoclonal Antibodies. Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune®* technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, MedImmune, LLC (a subsidiary of AstraZeneca), Amgen, Biogen Idec, Inc., Novartis, Roche, Genentech, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences. As noted above, AstraZeneca and Astellas have licensed our *VelocImmune* technology as part of their internal antibody development programs.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. The Pfizer antibody against NGF is in Phase 3 clinical trials for the treatment of pain due to osteoarthritis. Roche is marketing an antibody against the interleukin-6 receptor (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor Ortho Biotech, Inc. and Bristol Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, Inc., has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against interleukin-4 in clinical development. Amgen previously had an antibody against the interleukin-4 receptor in clinical development for the treatment of asthma. We believe that several companies, including Amgen, have development programs for antibodies against PCSK9.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, the announcement may have an adverse effect on our operations or future prospects or on the market price of our Common Stock.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

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Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see "Risk Factors – *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 policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. As of December 31, 2009, we held an ownership interest in a total of approximately 180 issued patents in the United States and over 750 issued patents in foreign countries with respect to our products and technologies. In addition, we held an ownership interest in hundreds of patent applications in the United States and foreign countries.

Our patent portfolio includes granted patents and pending patent applications covering our *VelociSuite*™ technologies, including our *VelocImmune*® mouse platform which produces fully human monoclonal antibodies. Our issued patents covering these technologies generally expire between 2020 and 2030. However, we continue to file patent applications directed to improvements to these technology platforms.

Our patent portfolio also includes issued patents and pending applications relating to our marketed product, ARCALYST® (rilonacept), and our product candidates in clinical development. These patents cover the proteins and DNA encoding the proteins, manufacturing patents, method of use patents, pharmaceutical compositions, as well as various methods of using the products. For each of ARCALYST and our late-stage clinical candidates, aflibercept (VEGF Trap) and VEGF Trap-Eye, these patents generally expire between 2020 and 2026. However, the projected patent terms may be subject to extension based on potential patent term extensions in countries where such extensions are available.

We also are the nonexclusive licensee of a number of additional patents and patent applications. In July 2008 we entered into an Amended and Restated Non-Exclusive License Agreement with Cellectis S.A. pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to this agreement, we agreed to pay Cellectis a low, single-digit royalty based on any future revenue received by us from any future licenses or sales of our *VelociGene*® or *VelocImmune* products or services. No royalties are payable on any revenue from commercial sales of antibodies from our *VelocImmune* technology, including antibodies developed under our collaboration with sanofi-aventis. We also have non-exclusive license agreements with Amgen and other organizations for patent rights related to ARCALYST. In exchange for these licenses, we pay a mid-single digit royalty on net sales of ARCALYST.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights is expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST and our product candidates (see "Risk Factors – *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.*"). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and

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foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST® (rilonacept) product sales for the treatment of CAPS, (iii) licensing agreements to utilize our *VelocImmune®* technology, and (iv) the supply of specified, ordered research materials using our *VelociGene®* technology platform.

Employees

As of December 31, 2009, we had 1,029 full-time employees, of whom 192 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

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Available Information

We make available free of charge on or through our Internet website (*http://www.regeneron.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Results and Need for Additional Financing

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

From inception on January 8, 1988 through December 31, 2009, we had a cumulative loss of $941.1 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

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

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, 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 December 31, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled $390.0 million and represented 53% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled $181.3 million at December 31, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated

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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 2009, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and rilonacept in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or 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.

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 (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

Rilonacept is in Phase 3 clinical trials for two different gout indications – the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that rilonacept will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of rilonacept in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

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

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

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could harm the future development of our product candidate(s) and our business may be materially harmed.

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

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible 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,

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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 and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor, ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

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

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

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Risks Related to Intellectual Property

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

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

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

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

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

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

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

Regulatory and Litigation Risks

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

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

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

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

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

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If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states and also at the federal level. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

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

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

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

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

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an 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;

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- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and current pending legislation which would ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to $1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding

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that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

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

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

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

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST 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

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and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

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

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

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

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST 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

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capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009 we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

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

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors,

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and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

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

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST. The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop rilonacept for the treatment of certain gout indications. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over rilonacept in gout by some physicians, which would make it difficult for us to successfully commercialize rilonacept in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize rilonacept in these diseases.

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

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of rilonacept for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray

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or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST in the United States for the treatment of a group of rare genetic disorders called CAPS. We recently received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

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

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

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

Risk Related to Employees

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

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

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Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

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

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2009, our four largest shareholders plus Leonard Schleifer, M.D, Ph.D., our Chief Executive Officer, beneficially owned 41.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2009. As of December 31, 2009, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.8% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2009, holders of Class A Stock held 22.2% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate

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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 December 31, 2009:

- our current executive officers and directors beneficially owned 14.0% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2009, and 28.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2009; and
- our four largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 41.6% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2009. In addition, these five shareholders held 48.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2009.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for 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."*

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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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main lease in Tarrytown, New York, as amended, we lease 537,100 square feet of laboratory and office facilities, including approximately 406,200 square feet of space that we currently occupy and approximately 130,900 square feet of additional new space that is under construction and expected to be completed in mid-2011. The term of the lease will expire in June 2024. The lease contains three renewal options to extend the term of the lease by five years each and early termination options on approximately 290,400 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Monthly lease payments on the new space that is under construction will commence in January 2011 and additional charges for utilities, taxes and operating expenses commenced in January 2010.

In December 2009, we leased, on a short-term basis, approximately 16,700 square feet of laboratory and office space at our current Tarrytown location while construction is completed on our additional new facilities, as described above. We expect to lease this space through May 2011. We also entered into a separate agreement in December 2009 to lease approximately 6,600 additional square feet of laboratory and office space at our current Tarrytown location in facilities that are now under construction and expected to be completed in mid-2010. The term of this lease will expire in August 2011 after which time we have the option to include this space in our main Tarrytown lease, as described above. Monthly lease payments on this additional space that is under construction are expected to commence in June 2010.

In October 2008, we entered into an operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The term of the lease expires in July 2011.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space.

The following table summarizes the information regarding our current real property leases:

Location	Square Footage	Expiration	Current Monthly Base Rental Charges[1]	Renewal Option Available
Tarrytown, New York[2]	389,500	June, 2024	$1,115,000	Three 5-year terms
Tarrytown, New York[3]	130,900	June, 2024	—	Three 5-year terms
Tarrytown, New York[2]	16,700	May, 2011	$ 7,900	None
Tarrytown, New York[4]	6,600	August, 2011	—	Incorporate into main Tarrytown lease
Bridgewater, New Jersey[5]	14,100	July 2011	$ 21,700	None

(1) Excludes additional charges for utilities, real estate taxes, and operating expenses, as defined, included in our rent.

(2) Represents space currently occupied in Tarrytown, New York as described above.

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(3) Represents space currently under construction. Rental payments will commence in January 2011.

(4) Represents space currently under construction. Rental payments will commence in June 2010.

(5) Relates to sublease in Bridgewater, New Jersey as described above.

We believe that our existing owned and leased facilities are adequate for ongoing research, development, manufacturing, and administrative activities. In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

ITEM 3. 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended December 31, 2009.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market:

	High	Low
2008		
First Quarter	$25.25	$15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62
2009		
First Quarter	$20.08	$11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02

As of February 12, 2010, there were 462 shareholders of record of our Common Stock and 39 shareholders of record of our Class A Stock.

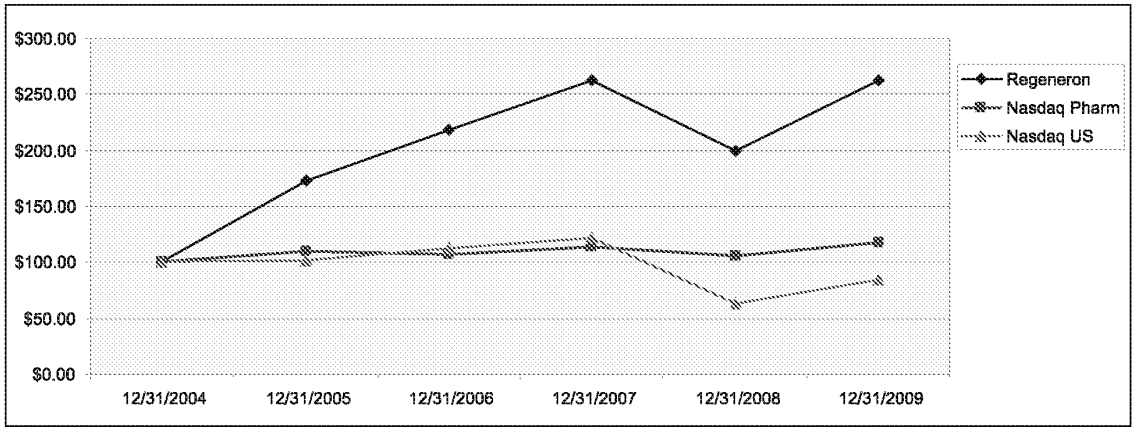
We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

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STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The Nasdaq Pharmaceuticals Stocks Index and (ii) The Nasdaq Stock Market (U.S.) Index for the period from December 31, 2004 through December 31, 2009. The comparison assumes that $100 was invested on December 31, 2004 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009
Regeneron	$100.00	$172.64	$217.92	$262.21	$199.35	$262.54
Nasdaq Pharm	100.00	110.12	107.79	113.36	105.48	118.52
Nasdaq US	100.00	102.13	112.19	121.68	62.73	84.28

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ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2009, 2008, and 2007 and at December 31, 2009 and 2008 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2006 and 2005 and at December 31, 2007, 2006, and 2005 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
		*Revised**	*Revised**		
		(In thousands, except per share data)			
Statement of Operations Data					
Revenues					
Collaboration revenue	$314,457	$185,138	$ 87,648	$ 47,763	$ 49,372
Technology licensing	40,013	40,000	28,421		
Contract manufacturing				12,311	13,746
Net product sales	18,364	6,249			
Contract research and other	6,434	7,070	8,955	3,373	3,075
	379,268	238,457	125,024	63,447	66,193
Expenses					
Research and development	398,762	274,903	202,468	137,064	155,581
Contract manufacturing				8,146	9,557
Selling, general, and administrative	52,923	48,880	37,929	25,892	25,476
Cost of goods sold	1,686	923			
	453,371	324,706	240,397	171,102	190,614
Income (loss) from operations	(74,103)	(86,249)	(115,373)	(107,655)	(124,421)
Other income (expense)					
Other contract income					30,640
Investment income	4,488	18,161	20,897	16,548	10,381
Interest expense	(2,337)	(7,752)	(12,043)	(12,043)	(12,046)
Loss on early extinguishment of debt		(938)			
	2,151	9,471	8,854	4,505	28,975
Net loss before income tax expense and cumulative effect of a change in accounting principle	(71,952)	(76,778)	(106,519)	(103,150)	(95,446)
Income tax (benefit) expense	(4,122)	2,351			
Net loss before cumulative effect of a change in accounting principle	(67,830)	(79,129)	(106,519)	(103,150)	(95,446)
Cumulative effect of a change in accounting principle related to share-based payments				813	
Net loss	$ (67,830)	$ (79,129)	$(106,519)	$(102,337)	$ (95,446)
Net loss per share, basic and diluted:					
Net loss before cumulative effect of a change in accounting principle	$ (0.85)	$ (1.00)	$ (1.61)	$ (1.78)	$ (1.71)
Cumulative effect of a change in accounting principle related to share-based payments				0.01	
Net loss	$ (0.85)	$ (1.00)	$ (1.61)	$ (1.77)	$ (1.71)

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	At December 31,				
	2009	2008	2007	2006	2005
		*Revised**	*Revised**		
			(In thousands)		
Balance Sheet Data					
Cash, cash equivalents, restricted cash, and marketable securities (current and non-current)	$390,010	$527,461	$ 846,279	$ 522,859	$ 316,654
Total assets	741,202	724,220	957,881	585,090	423,501
Notes payable - current portion			200,000		
Notes payable - long-term portion				200,000	200,000
Facility lease obligations	109,022	54,182	21,623		
Stockholders' equity	396,762	421,514	459,348	216,624	114,002

* We have revised our financial statements at December 31, 2008 and 2007 and for the years ended December 31, 2008 and 2007 in connection with the application of authoritative guidance issued by the Financial Accounting Standards Board (FASB) to our December 2006 lease, as amended, of laboratory and office facilities in Tarrytown, New York. The revisions, and a description of the basis for the revisions, are more fully described in Note 11 to our audited financial statements included elsewhere in this report.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are 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 eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with sanofi-aventis. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN727, an antibody to PCSK9, which is being developed for LDL cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our early stage clinical programs are fully human antibodies that are being developed 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.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

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From inception on January 8, 1988 through December 31, 2009, we had a cumulative loss of $941.1 million. In the absence of significant revenues from the commercialization of ARCALYST® (rilonacept) or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and rilonacept in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our collaborators, including sanofi-aventis, (ii) funding from our collaborators and licensees in the form of up-front and milestone payments, research progress payments, and payments for our research and development activities, and (iii) a private placement of convertible debt, which was repaid in full during 2008.

In 2009, our research and development expenses totaled $398.8 million. In 2010, we expect these expenses to increase substantially as we continue to expand our research and preclinical and clinical development activities, primarily in connection with our antibody collaboration with sanofi-aventis.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2009 was 980 compared with 810 in 2008 and 627 in 2007. In 2009 and 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2007 our average headcount increased primarily to support our expanded development programs for VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials. In 2010, we expect our average headcount to increase to approximately 1,350-1,400, primarily to support the further expansion of our research, development, and marketing activities as described above, especially in connection with our antibody collaboration with sanofi-aventis.

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The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2009 and 2010 to date were, and plans for the remainder of 2010 are, as follows:

Clinical Program	2009 and 2010 Events to Date	2010 Plans
Rilonacept (also known as IL-1 Trap)	• Initiated patient enrollment in two Phase 3 trials (PRE-SURGE 1 and PRE-SURGE 2) evaluating rilonacept in the prevention of gout flares associated with the initiation of urate-lowering drug therapy; completed patient enrollment in the PRE-SURGE 1 study • Initiated and completed patient enrollment in a Phase 3 study (SURGE) evaluating rilonacept in the treatment of acute gout flares	• Report data from SURGE and PRE-SURGE 1 during the first half of 2010 • Complete patient enrollment of the remaining Phase 3 studies in gout
VEGF Trap-Eye (intravitreal injection)	• Completed patient enrollment in the Phase 3 wet AMD program (VIEW 1 and VIEW 2) • Initiated a Phase 3 CRVO program • Reported results from the Phase 2 DME trial	• Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 • Complete patient enrollment of the Phase 3 CRVO trials
Aflibercept (VEGF Trap – Oncology)	• Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer and prostate cancer • Initiated a Phase 2 1st line study in metastatic colorectal cancer in combination with chemotherapy • Reported results of a Phase 2 single-agent study in symptomatic malignant ascites (SMA) • Discontinued a Phase 3 study in metastatic pancreatic cancer in combination with chemotherapy	• Complete patient enrollment in the Phase 3 study in colorectal cancer • During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study in colorectal cancer
Monoclonal Antibodies	• REGN475: Initiated a Phase 1 trial in healthy volunteers, a dose-ranging, proof-of-concept study in osteoarthritis of the knee, and additional proof-of-concept studies in pain associated with sciatica, vertebral fracture, chronic pancreatitis, and thermal injury • REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis • REGN421: Initiated a Phase 1 trial in oncology • REGN727: Initiated a Phase 1 program in healthy volunteers • REGN668: Initiated a Phase 1 program in healthy volunteers	• REGN475: Report data from the study in osteoarthritis of the knee during the first half of 2010 and from the study in sciatica during the second half of 2010 • REGN727: Report proof-of-concept data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction • REGN668: Initiate a Phase 2 program in the treatment of a chronic allergic condition • REGN88: Report data from a Phase 1 trial in rheumatoid arthritis • Advance additional antibody candidate(s) into clinical development

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Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 2 to our Financial Statements, beginning on page F-7. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- It requires an assumption (or assumptions) regarding a future outcome; and
- Changes in the estimate or the use of different assumptions to prepare the estimate could have a material effect on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our financial statements, the resulting changes could have a material adverse effect on our results of operations, and in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our financial statements are described below.

Revenue Recognition

Collaboration Revenue

We earn collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize our technology platforms. We currently have collaboration agreements with sanofi-aventis and Bayer HealthCare. The terms of collaboration agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as collaboration revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse.

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In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. For example, during the fourth quarter of 2008, we extended our estimated performance period in connection with the up-front and non-substantive milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened our estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in our estimates resulted in the recognition of $0.4 million less in collaboration revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. In addition, in connection with amendments to expand and extend our antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, we extended our estimated performance period related to the up-front payment previously received from sanofi-aventis pursuant to the companies' antibody collaboration. The effect of this change in estimate resulted in the recognition of $0.6 million less in collaboration revenue in the fourth quarter of 2009, compared to amounts recognized in each of the prior three quarters of 2009. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

Product Revenue

In March 2008, ARCALYST® (rilonacept) became available for prescription in the United States for the treatment of CAPS. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. Since we have limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or we can reasonably estimate returns and (ii) rebates have been processed or we can reasonably estimate rebates. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

Clinical Trial Expenses

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

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For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue expense on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2009, 2008, or 2007.

Stock-based Employee Compensation

We recognize stock-based compensation expense for grants of stock option awards and restricted stock to employees and non-employee members of our board of directors under our long-term incentive plans based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The assumptions used in computing the fair value of option awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside of our control. Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in future periods.

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options' performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation that we recognize in future periods related to performance-based options.

Marketable Securities

We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider our marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board (FASB). These assets 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 marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that may be charged against income.

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On a quarterly basis, we review our portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. Such factors include the length of time and the extent to which market value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. With respect to debt securities, this review process also includes an evaluation of our intent to sell an individual debt security or our need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of our ability and intent to hold the securities until their full value can be recovered. This review is subjective and requires a high degree of judgment.

As a result of our quarterly reviews of our marketable securities portfolio, during 2009, 2008, and 2007 we recorded charges for other-than-temporary impairment of our marketable securities totaling $0.1 million, $2.5 million, and $5.9 million, respectively. The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

Depreciation of Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods.

Results of Operations

Years Ended December 31, 2009 and 2008

Net Loss

Regeneron reported a net loss of $67.8 million, or $0.85 per share (basic and diluted), for the year ended December 31, 2009, compared to a net loss of $79.1 million, or $1.00 per share (basic and diluted) for 2008. The decrease in our net loss in 2009 was principally due to higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis, receipt of a $20.0 million substantive performance milestone payment in connection with our VEGF Trap-Eye collaboration with Bayer HealthCare, and higher ARCALYST® (rilonacept) sales, partially offset by higher research and development expenses, as detailed below.

Revenues

Revenues in 2009 and 2008 consist of the following:

(In millions)	2009	2008
Collaboration revenue		
Sanofi-aventis	$247.2	$154.0
Bayer HealthCare	67.3	31.2
Total collaboration revenue	314.5	185.2
Technology licensing revenue	40.0	40.0
Net product sales	18.4	6.3
Contract research and other revenue	6.4	7.0
Total revenue	$379.3	$238.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

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Sanofi-aventis Collaboration Revenue *(In millions)*	Years ended December 31, 2009	2008
Aflibercept:		
Regeneron expense reimbursement	$ 26.6	$ 35.6
Recognition of deferred revenue related to up-front payments	9.9	8.8
Total aflibercept	36.5	44.4
Antibody:		
Regeneron expense reimbursement	198.1	97.9
Recognition of deferred revenue related to up-front payment	9.9	10.5
Recognition of revenue related to *VelociGene*® agreement	2.7	1.2
Total antibody	210.7	109.6
Total sanofi-aventis collaboration revenue	$247.2	$154.0

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in 2009 compared to 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 2009 compared to 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 December 31, 2009, $42.5 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 2009, sanofi-aventis' reimbursement of our antibody expenses consisted of $99.8 million under the discovery agreement and $98.3 million of development costs under the license agreement, compared to $72.2 million and $25.7 million, respectively, in 2008. The higher reimbursement amounts in 2009 compared to 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement. Recognition of deferred revenue related to sanofi-aventis' $85.0 million up-front payment decreased in 2009 compared to 2008 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. As of December 31, 2009, $63.7 million of the original $85.0 million up-front payment was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene* agreement with sanofi-aventis. In 2009 and 2008, we recognized $2.7 million and $1.2 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable $75.0 million up-front payment and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue *(In millions)*	Years ended December 31, 2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$37.4	$18.8
Substantive performance milestone payment	20.0	
Recognition of deferred revenue related to up-front and other milestone payments	9.9	12.4
Total Bayer HealthCare collaboration revenue	$67.3	$31.2

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in 2009 compared to 2008. Under the terms of the collaboration, in 2009, all agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally. In 2008, the first $70.0 million of agreed-upon VEGF Trap-Eye development expenses were shared equally, and we were solely responsible for up to the next $30.0 million. During the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which reduced the amount of cost-sharing revenue we earned from Bayer HealthCare in 2008. In addition, cost-sharing revenue increased in 2009, compared to 2008, due

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to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. In July 2009, we received a $20.0 million substantive performance 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, which was recognized as collaboration revenue. Recognition of deferred revenue related to the up-front and August 2007 milestone payments from Bayer HealthCare decreased in 2009 from 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 December 31, 2009, $56.8 million of these up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In both 2009 and 2008, we recognized $40.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In 2009 and 2008, we recognized as revenue $18.4 million and $6.3 million, respectively, of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At December 31, 2009, deferred revenue related to ARCALYST net product sales totaled $4.8 million.

Contract Research and Other Revenue

Contract research and other revenue in 2009 and 2008 included $5.5 million and $4.9 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $453.4 million in 2009 from $324.7 million in 2008. Our average headcount in 2009 increased to 980 from 810 in 2008 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2009 and 2008 include a total of $31.3 million and $32.5 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the year ended December 31, 2009		
Expenses	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
(In millions)			
Research and development	$380.0	$18.8	$398.8
Selling, general, and administrative	40.4	12.5	52.9
Cost of goods sold	1.7		1.7
Total operating expenses	$422.1	$31.3	$453.4

	For the year ended December 31, 2008		
Expenses	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
(In millions)			
Research and development	$255.9	$19.0	$274.9
Selling, general, and administrative	35.4	13.5	48.9
Cost of goods sold	0.9		0.9
Total operating expenses	$292.2	$32.5	$324.7

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The decrease in total Non-cash Compensation Expense in 2009 was primarily attributable to the lower fair market value of our Common Stock on the date of our annual employee option grants made in December 2008 as compared to the fair market value of annual employee option grants made in recent years prior to 2008.

Research and Development Expenses

Research and development expenses increased to $398.4 million in 2009 from $274.9 million in 2008. The following table summarizes the major categories of our research and development expenses in 2009 and 2008:

	Year Ended December 31,		
Research and Development Expenses	**2009**	**2008**	**Increase**
(In millions)			
Payroll and benefits[1]	$ 99.9	$ 81.7	$ 18.2
Clinical trial expenses	111.6	49.3	62.3
Clinical manufacturing costs[2]	66.7	53.8	12.9
Research and preclinical development costs	42.3	29.6	12.7
Occupancy and other operating costs	40.6	30.5	10.1
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	37.7	30.0	7.7
Total research and development	$398.8	$274.9	$123.9

(1) Includes $16.2 million and $16.7 million of Non-cash Compensation Expense in 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 $2.6 million and $2.3 million of Non-cash Compensation Expense in 2009 and 2008, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, DA VINCI trial in DME, and COPERNICUS trial in CRVO, (ii) rilonacept, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of rilonacept 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, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

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We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	Year ended December 31, 2009	2008	Increase (Decrease)
(In millions)			
Rilonacept	$ 67.7	$ 39.2	$ 28.5
VEGF Trap-Eye	109.8	82.7	27.1
Aflibercept	23.3	32.1	(8.8)
REGN88	36.9	21.4	15.5
Other antibody candidates in clinical development	74.4	27.4	47.0
Other research programs & unallocated costs	86.7	72.1	14.6
Total research and development expenses	$398.8	$274.9	$123.9

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of rilonacept, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates 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 shipped $20.0 million and $10.7 million of ARCALYST to our U.S. distributors in 2009 and 2008, respectively.

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Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $52.9 million in 2009 from $48.9 million in 2008. In 2009, we incurred (i) higher compensation expense, (ii) higher patent-related costs, (iii) higher facility-related costs due primarily to increases in administrative headcount, and (iv) higher patient assistance costs related to ARCALYST® (rilonacept). These increases were partially offset by (i) lower marketing costs related to ARCALYST, (ii) a decrease in administrative recruitment costs, and (iii) lower professional fees related to various corporate matters.

Cost of Goods Sold

During 2008, we began recognizing revenue and cost of goods sold from net 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 included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold in 2009 and 2008 was $1.7 million and $0.9 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST commercial supplies.

Other Income and Expense

Investment income decreased to $4.5 million in 2009 from $18.2 million in 2008, due primarily to lower yields on, and lower balances of, cash and marketable securities. In addition, in 2009 and 2008, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2009 and 2008, we recognized charges of $0.1 million and $2.5 million, respectively, related to these securities, which we considered to be other than temporarily impaired. In 2009 and 2008, these charges were either wholly or partially offset by realized gains of $0.2 million and $1.2 million, respectively, on sales of marketable securities during the year.

Interest expense decreased to $2.3 million in 2009 from $7.8 million in 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 2008 related to $200.0 million of 5.5% Convertible Senior Subordinated Notes until they were retired. 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 these 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. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Income Tax (Benefit) Expense

In 2009, we recognized a $4.1 million income tax benefit, consisting primarily of (i) $2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows us to claim a refund of U.S. federal alternative minimum tax that we paid in 2008, as described below, and (ii) $0.7 million resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allows us to claim a refund for a portion of our unused pre-2006 research tax credits.

In 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of $3.1 million, which relates to U.S. federal and New York State alternative minimum taxes and included $0.2 million of interest and penalties. This expense was partly offset by a $0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

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Years Ended December 31, 2008 and 2007

Net Loss

Regeneron reported a net loss of $79.1 million, or $1.00 per share (basic and diluted), for the year ended December 31, 2008, compared to a net loss of $106.5 million, or $1.61 per share (basic and diluted) for 2007. The decrease in net loss was principally due to revenues earned in 2008 in connection with our November 2007 antibody collaboration with sanofi-aventis, partly offset by higher research and development expenses.

Revenues

Revenues in 2008 and 2007 consist of the following:

(In millions)	2008	2007
Collaboration revenue		
Sanofi-aventis	$154.0	$ 51.7
Bayer HealthCare	31.2	35.9
Total collaboration revenue	185.2	87.6
Technology licensing revenue	40.0	28.4
Net product sales	6.3	
Contract research and other revenue	7.0	9.0
Total revenue	$238.5	$125.0

Sanofi-Aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the aflibercept collaboration and $85.0 million related to the antibody collaboration.

	Years ended December 31,	
Sanofi-aventis Collaboration Revenue	**2008**	**2007**
(In millions)		
Aflibercept:		
Regeneron expense reimbursement	$ 35.6	$38.3
Recognition of deferred revenue related to up-front payments	8.8	8.8
Total aflibercept	44.4	47.1
Antibody:		
Regeneron expense reimbursement	97.9	3.7
Recognition of deferred revenue related to up-front payment	10.5	0.9
Recognition of revenue related to *VelociGene*® agreement	1.2	
Total antibody	109.6	4.6
Total sanofi-aventis collaboration revenue	$154.0	$51.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in 2008 compared to 2007, primarily due to lower costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue relates to sanofi-aventis' up-front aflibercept payments. As of December 31, 2008, $52.4 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 2008, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of $72.2 million under the discovery agreement and $25.7 million of development costs, related primarily to REGN88, under the license agreement, compared to $3.0 million and $0.7 million, respectively, in 2007. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' $85.0 million up-front payment. As of December 31, 2008, $73.6 million of this up-front payment was deferred and will be recognized as revenue in future periods.

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In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. In 2008, we recognized $1.2 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable $75.0 million up-front payment and a $20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

	Years ended December 31,	
Bayer HealthCare Collaboration Revenue	**2008**	**2007**
(In millions)		
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$18.8	$20.0
Recognition of deferred revenue related to up-front and milestone payments	12.4	15.9
Total Bayer HealthCare collaboration revenue	$31.2	$35.9

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The $75.0 million up-front licensing and $20.0 million milestone payments from Bayer HealthCare are being recognized as collaboration revenue over the related estimated performance period. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, 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. In the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased in 2008 compared to 2007. Under the terms of the collaboration, in 2008, the first $70.0 million of agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally, and we were solely responsible for up to the next $30.0 million. Since both we and Bayer HealthCare incurred higher VEGF Trap-Eye development expenses in 2008 compared to 2007, during the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which partly contributed to the revenue decrease in 2008 compared to 2007. In addition, the decrease was due in part to the cumulative catch-up recognized in 2007 from the inception of the collaboration in October 2006, as described above. Recognition of deferred revenue related to Bayer HealthCare's $75.0 million up-front and $20.0 million milestone payments also decreased in 2008 from 2007 as a result of the cumulative catch-up. As of December 31, 2008, $66.7 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the $20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In 2008 and 2007, we recognized $40.0 million and $28.4 million, respectively, of technology licensing revenue related to these agreements.

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Net Product Sales

In 2008, we recognized as revenue $6.3 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled $4.0 million.

Contract Research and Other Revenue

Contract research and other revenue in 2008 and 2007 included $4.9 million and $5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to $324.7 million in 2008 from $240.4 million in 2007. Our average headcount in 2008 increased to 810 from 627 in 2007 principally as a result of our expanding research and development activities which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2008 and 2007 include a total of $32.5 million and $28.1 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the year ended December 31, 2008		
Expenses	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
(In millions)			
Research and development	$255.9	$19.0	$274.9
Selling, general, and administrative	35.4	13.5	48.9
Cost of goods sold	0.9		0.9
Total operating expenses	$292.2	$32.5	324.7

	For the year ended December 31, 2007		
Expenses	**Expenses before inclusion of Non-cash Compensation Expense**	**Non-cash Compensation Expense**	**Expenses as Reported**
(In millions)			
Research and development	$186.3	$16.2	$202.5
Selling, general, and administrative	26.0	11.9	37.9
Total operating expenses	$212.3	$28.1	$240.4

The increase in total Non-cash Compensation Expense in 2008 was partly attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2007 in comparison to the fair market value of annual employee option grants made in recent years prior to 2006. In addition, Non-cash Compensation Expense in 2008 and 2007 included $2.2 million and $0.1 million, respectively, in connection with a December 2007 Restricted Stock award.

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Research and Development Expenses

Research and development expenses increased to $274.9 million in 2008 from $202.5 million in 2007. The following table summarizes the major categories of our research and development expenses in 2008 and 2007:

Research and Development Expenses	Year ended December 31, 2008	2007	Increase
(In millions)			
Payroll and benefits[1]	$ 81.7	$ 60.6	$21.1
Clinical trial expenses	49.3	37.6	11.7
Clinical manufacturing costs[2]	53.8	47.0	6.8
Research and preclinical development costs	29.6	23.2	6.4
Occupancy and other operating costs	30.5	23.5	7.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses[3]	30.0	10.6	19.4
Total research and development	$274.9	$202.5	$72.4

(1) Includes $16.7 million and $13.2 million of Non-cash Compensation Expense in 2008 and 2007, 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 $2.3 million and $3.0 million of Non-cash Compensation Expense in 2008 and 2007, respectively.

(3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing cost-sharing of our and Bayer Healthcare's VEGF Trap-Eye development expenses. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, which includes our VIEW 1 trial in wet AMD, (ii) rilonacept, which includes our Phase 2 gout flare prevention clinical study, and (iii) monoclonal antibodies, which includes REGN88 as well as clinical-related preparatory activities for REGN421. Clinical manufacturing costs increased due primarily to higher expenses related to VEGF Trap-Eye and monoclonal antibodies, including REGN88. These increases were partially offset by a reduction in manufacturing costs associated with rilonacept and aflibercept. 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 Bayer HealthCare initiated in 2008.

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We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	Year ended December 31, 2008	2007	Increase (Decrease)
(In millions)			
Rilonacept	$ 39.2	$ 38.1	$ 1.1
Aflibercept	32.1	33.7	(1.6)
VEGF Trap-Eye	82.7	53.7	29.0
REGN88	21.4	13.6	7.8
Other research programs & unallocated costs	99.5	63.4	36.1
Total research and development expenses	$274.9	$202.5	$72.4

For the reasons described above in Results of Operations for the years ended December 31, 2009 and 2008, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. We shipped $10.7 million of ARCALYST to our U.S. distributors in 2008.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $48.9 million in 2008 from $37.9 million in 2007. In 2008, we incurred $5.2 million of selling expenses related to ARCALYST for the treatment of CAPS. General and administrative expenses increased in 2008 due to (i) higher compensation expense primarily resulting from increases in administrative headcount to support our expanded research and development activities, (ii) higher recruitment and related costs associated with expanding our headcount, (iii) higher fees for professional services related to various general corporate matters, and (iv) higher administrative facility-related costs.

Cost of Goods Sold

During 2008, we began recognizing revenue and cost of goods sold from net 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 in 2008 was $0.9 million and consisted primarily of royalties and other period costs related to ARCALYST commercial supplies.

Other Income and Expense

Investment income decreased to $18.2 million in 2008 from $20.9 million in 2007, due primarily to lower yields on our cash and marketable securities. In addition, in 2008 and 2007, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2008 and 2007, we recognized charges of $2.5 million and $5.9 million, respectively, related to these securities, which we considered to be other than temporarily impaired. In 2008, these charges were partially offset by realized gains of $1.2 million on sales of marketable securities during the year.

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Interest expense of $7.8 million and $12.0 million in 2008 and 2007, respectively, was attributable to our 5.5% Convertible Senior Subordinated Notes due October 17, 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 these 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. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 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, that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of $3.1 million, which relates to U.S. federal and New York State alternative minimum taxes and included $0.2 million of interest and penalties. This expense was partially offset by a $0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Revision of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

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.

As previously disclosed in our Quarterly Reports on Form 10-Q for the quarters ended June 30 and September 30, 2009, 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, 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.

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For comparative purposes, the impact of the above described revisions to our balance sheet as of December 31, 2008 is as follows:

Balance Sheet Impact at December 31, 2008
(In millions)

	December 31, 2008
As originally reported	
Property, plant, and equipment, net	$ 87.9
Total assets	670.0
Other long-term liabilities	5.1
Total liabilities	251.2
Accumulated deficit	(875.9)
Total stockholders' equity	418.8
Total liabilities and stockholders' equity	670.0
As revised	
Property, plant, and equipment, net	$ 142.0
Total assets	724.2
Facility lease obligation	54.2
Other long-term liabilities	2.4
Total liabilities	302.7
Accumulated deficit	(873.3)
Total stockholders' equity	421.5
Total liabilities and stockholders' equity	724.2

For comparative purposes, the impact of the above described revisions to our statements of operations for the period(s) set forth below is as follows:

Statements of Operations Impact for the years ended December 31, 2008 and 2007
(In millions, except per share data)

	December 31,	
	2008	2007
As originally reported		
Research and development expenses	$278.0	$ 201.6
Selling, general, and administrative expenses	49.3	37.9
Total expenses	328.3	239.5
Net loss	(82.7)	(105.6)
Net loss per share, basic and diluted	$ (1.05)	$ (1.59)
As revised		
Research and development expenses	$274.9	$ 202.5
Selling, general, and administrative expenses	48.9	37.9
Total expenses	324.7	240.4
Net loss	(79.1)	(106.5)
Net loss per share, basic and diluted	$ (1.00)	$ (1.61)

These revised amounts are reflected in this Annual Report on Form 10-K for the year ended December 31, 2009.

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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 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.

Sources and Uses of Cash for the Years Ended December 31, 2009, 2008, and 2007

At December 31, 2009, we had $390.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with $527.5 million at December 31, 2008 and $846.3 million at December 31, 2007. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made $20.0 million annual, non-refundable payments to us in each of 2009, 2008, and 2007. In July 2009 and August 2007, we received $20.0 million milestone payments from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO and wet AMD, respectively. In December 2007, we received an $85.0 million upfront payment in connection with our original antibody collaboration agreement with sanofi-aventis. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of $312.0 million.

Cash (Used in) Provided by Operations

Net cash used in operations was $72.2 million in 2009 and $89.1 million in 2008, and net cash provided by operations was $27.4 million in 2007. Our net losses of $67.8 million in 2009, $79.1 million in 2008, and $106.5 million in 2007 included $31.3 million, $32.5 million, and $28.1 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of $14.2 million, $11.3 million, and $11.5 million in 2009, 2008, and 2007, respectively.

At December 31, 2009, accounts receivable increased by $30.4 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue balances at December 31, 2009 decreased by $27.5 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. Accounts payable, accrued expenses, and other liabilities increased $13.0 million at December 31, 2009, compared to end-of-year 2008, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses, which were partially offset by an $8.6 million decrease in the cost-sharing payment due to Bayer HealthCare in connection with our VEGF Trap-Eye collaboration.

At December 31, 2008, accounts receivable increased by $16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue balances at December 31, 2008 decreased by $26.8 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 partially offset by the deferral of $4.0 million of ARCALYST® (rilonacept) net product sales at December 31, 2008.

At December 31, 2007, accounts receivable increased by $10.8 million, compared to end-of-year 2006, due to higher receivable balances related to our collaborations with sanofi-aventis and Bayer HealthCare. Also, prepaid expenses and other assets increased $9.6 million at December 31, 2007, compared to end-of-year 2006, due primarily to higher prepaid clinical trial costs. Our deferred revenue balances at December 31, 2007 increased by $89.8 million, compared to end-of-year 2006, due primarily to (i) the $85.0 million up-front payment received from sanofi-aventis, (ii) the $20.0 million milestone payment from Bayer HealthCare which was not considered to be substantive for revenue recognition purposes and, therefore, fully deferred, and (iii) the two $20.0 million licensing payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from amortization of these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased $19.1 million at December 31, 2007, compared to end-of-year 2006, primarily due to a $4.9 million cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration and higher accruals in 2007 for payroll costs and clinical-related expenses.

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The majority of our cash expenditures in 2009, 2008, and 2007 were to fund research and development, primarily related to our clinical programs and our preclinical human monoclonal antibody programs. In 2008 and 2007, we made interest payments totaling $9.3 million and $11.0 million, respectively, on our convertible senior subordinated notes. The convertible notes were repaid in full in 2008.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $146 thousand in 2009 and $30.8 million in 2008, and net cash used in investing activities was $85.7 million in 2007. In 2009 and 2008, sales or maturities of marketable securities exceeded purchases by $97.4 million and $65.7 million, respectively, whereas in 2007, purchases of marketable securities exceeded sales or maturities by $67.3 million. Capital expenditures in 2009 and 2008 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease, as described below. Capital expenditures in 2007 included the purchase of land and a building in Rensselaer for $9.0 million.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $31.4 million in 2009 and $319.4 million in 2007, respectively, and net cash used in financing activities was $192.9 million in 2008. In 2009, we received a $23.6 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 second and third quarters of 2008, we repurchased $82.5 million in principal amount of our convertible senior subordinated notes for $83.3 million. The remaining $117.5 million of convertible notes were repaid in full upon their maturity in October 2008. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of $312.0 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were $8.6 million in 2009, $7.9 million in 2008, and $7.6 million in 2007.

Fair Value of Marketable Securities

At December 31, 2009 and 2008, we held marketable securities whose aggregate fair value totaled $181.3 million and $278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	2009		2008	
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. Treasury securities	$ 80.4	44%	$113.9	41%
U.S. government agency securities	29.6	16%	58.3	21%
U.S. government-guaranteed corporate bonds	48.7	27%	29.8	11%
U.S. government guaranteed collateralized mortgage obligations	3.7	2%	17.4	6%
Corporate bonds	10.3	6%	37.1	13%
Mortgage-backed securities	3.2	2%	10.0	4%
Other asset-backed securities			7.8	3%
Other	5.4	3%	3.7	1%
Total marketable securities	$181.3	100%	$278.0	100%

In addition, at December 31, 2009 and 2008, we had $208.7 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 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, reduced the risk profile, as well as the overall yield, of our portfolio during 2009.

In particular, we reduced the proportion of mortgage-backed securities in, and eliminated other asset-backed securities from, the portfolio since they had deteriorated in credit quality and declined in value due to higher delinquency rates on the underlying collateral supporting these securities. The mortgage-backed securities that we

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held at December 31, 2009 are backed by prime and sub-prime residential mortgages and home equity loans. The estimated fair value of our mortgage-backed securities generally ranged from 77% to 99% of par value at December 31, 2009. Our mortgage-backed securities are all senior tranches that are paid-down before other subordinated tranches as the loans in the underlying collateral are repaid. Through December 31, 2009, we continued to receive monthly payments of principal and interest on our mortgage-backed securities holdings. If the monthly principal and interest payments continue at approximately the current rate, we anticipate that all of the mortgage-backed securities in our portfolio will be repaid within the next two years, and most would be repaid in 2010. However, higher delinquency rates in the underlying collateral supporting mortgage-backed securities in our investment portfolio could result in future impairment charges related to these securities, which could be material.

We classify our investments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Changes in Level 3 marketable securities during the year ended December 31, 2009 and 2008 were as follows:

	Level 3 Marketable Securities	
(In millions)	2009	2008
Balance January 1	$ 0.1	$ 7.9
Settlements		(8.2)
Realized gain		1.1
Impairments	(0.1)	(0.7)
Balance December 31		$ 0.1

During the years ended December 31, 2009 and 2008, there were no transfers of marketable securities between Level 2 and Level 3 classifications.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

Collaborations with the sanofi-aventis Group

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for $45.0 million.

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable up-front payment to us, which was received in January 2006. Under the 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. We may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to

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$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2009, we and sanofi-aventis have incurred $598.4 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing.

Sanofi-aventis funded $26.6 million, $35.6 million, and $38.3 million, respectively, of our aflibercept development costs in 2009, 2008, and 2007, of which $3.6 million, $6.3 million, and $10.5 million, respectively, were included in accounts receivable as of December 31, 2009, 2008, and 2007. In addition, the up-front payments from sanofi-aventis of $80.0 million in September 2003 and $25.0 million in January 2006 were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2009, 2008, and 2007, we recognized $9.9 million, $8.8 million, and $8.8 million of revenue, respectively, related to these up-front payments.

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

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable up-front payment of $85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately $175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to $160 million per year of our antibody discovery activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. The discovery agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

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. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $140.2 million as of December 31, 2009)

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and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any.

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 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 only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's discovery agreement, sanofi-aventis will fund up to $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which $0.5 million were included in accounts receivable at December 31, 2009.

In 2009, 2008, and 2007, sanofi-aventis funded $99.8 million, $72.2 million, and $3.0 million, respectively, of our expenses under the collaboration's discovery agreement and $98.3 million, $25.7 million, and $0.7 million, respectively, of our development costs under the license agreement. Of these amounts, $57.9 million and $25.5 million were included in accounts receivable as of December 31, 2009 and 2008, respectively. The $85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as collaboration revenue over the period during which we expect to perform services. In 2009, 2008, and 2007, we recognized $9.9 million, $10.5 million, and $0.9 million of revenue, respectively, related to this up-front payment. In addition, reimbursements by sanofi-aventis of our costs to expand our manufacturing capacity will be recorded to deferred revenue and recognized prospectively as collaboration revenue over the same period applicable to recognition of the $85.0 million up-front payment, as described above.

In connection with the antibody collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which we expect to receive payments totaling a minimum of $21.5 million, of which $5.1 million had been received as of December 31, 2009.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of $312.0 million, or $26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us. This agreement, which was amended in November 2009, contains certain demand rights, "stand-still provisions", and other restrictions, which are more fully described in Note 12 to our Financial Statements.

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Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of $75.0 million. In August 2007, we received a $20.0 million milestone payment (which, for the purpose of revenue recognition, was not considered substantive) from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a $20.0 million substantive performance milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in CRVO. We are eligible to receive up to $70 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional $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.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $138.4 million at December 31, 2009) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from such commercialization in the United States. To date, we and Bayer HealthCare have initiated Phase 3 programs of VEGF Trap-Eye in wet AMD and CRVO and a Phase 2 clinical study in DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The $75.0 million up-front payment and the $20.0 million milestone payment received in August 2007 from Bayer HealthCare were recorded to deferred revenue. In 2009, 2008, and 2007, we recognized $9.9 million, $12.4 million, and $15.9 million, respectively, of revenue related to these deferred payments. The $20.0 million substantive performance milestone payment received from Bayer HealthCare in July 2009 was recognized as revenue in 2009.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2009, this resulted in a net payment by us of $0.3 million to Bayer HealthCare. In 2008, the first $70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next $30.0 million, which resulted in a net payment by us of $11.3 million to Bayer HealthCare. In 2007, the first $50.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next $40.0 million, which resulted in a net reimbursement of $9.4 million from Bayer HealthCare to us. At December 31, 2009 and 2008, accrued expenses included $1.2 million and $9.8 million, respectively, due to Bayer HealthCare.

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

License Agreements with AstraZeneca and Astellas

Under these non-exclusive license agreements, AstraZeneca and Astellas each made $20.0 million annual, non-refundable payments to us in each of 2009, 2008, and 2007. AstraZeneca and Astellas are each required to make up to three additional annual payments of $20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the next annual payment in 2010.

National Institutes of Health Grant

Under our five-year grant from the NIH, as amended, we are entitled to receive a minimum of $25.3 million over the five-year period beginning in September 2006, subject to compliance with the grant's terms and annual funding approvals, including $1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2009, 2008, and 2007, we recognized $5.5 million, $4.9 million, and $5.5 million, respectively, of

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revenue related to the NIH Grant, of which $1.2 million and $1.3 million, respectively, was receivable at the end of 2009 and 2008. In 2010, we expect to receive funding of approximately $5.5 million for reimbursement of Regeneron expenses related to the NIH Grant.

License Agreement with Cellectis

In July 2008, we and Cellectis S.A. entered into an Amended and Restated Non-Exclusive License Agreement. The amended license agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to the amended license agreement, in July 2008, we made a non-refundable $12.5 million payment to Cellectis and agreed to pay Cellectis a low single-digit royalty based on revenue received by us from any future licenses or sales of our *VelociGene®* or *VelocImmune®* products and services. No royalties are payable with respect to our *VelocImmune* license agreements with AstraZeneca and Astellas or our antibody collaboration with sanofi-aventis. In addition, no royalties are payable on any revenue from commercial sales of antibodies from our *VelocImmune* technology.

We are amortizing our $12.5 million payment to Cellectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis (as amended in November 2009). In 2009 and 2008, we recognized $2.3 million and $2.7 million, respectively, of expense related to the Cellectis agreement.

In July 2008, we and Cellectis also entered into a Subscription Agreement pursuant to which we purchased 368,301 ordinary shares of Cellectis in November 2008 at a price of EUR 8.63 per share (which was equivalent to $10.98 at the EUR exchange rate on the date of purchase).

Lease – Tarrytown, New York Facilities:

We lease approximately 537,100 square feet of laboratory and office space at facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended. These facilities include approximately 230,000 square feet of newly constructed space in two new buildings (Buildings A and B) that were completed during the third quarter of 2009 and, under a December 2009 amendment to the lease, approximately 130,900 square feet of additional new space that is under construction in a third new building (Building C), which is expected to be completed in mid-2011. The lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, as well as early termination options on approximately 290,400 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the lease are accounted for as operating leases. However, for the newly constructed space that we are leasing, we are deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance (as described above under "Revision of Previously Issued Financial Statements"), and the landlord's costs of constructing these new facilities are required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet.

In connection with the lease, in December 2006, we issued a letter of credit in the amount of $1.6 million to our landlord, which is collateralized by a $1.6 million bank certificate of deposit.

In connection with Buildings A and B, we capitalized our landlord's costs of constructing these new facilities, which totaled $58.2 million as of December 31, 2009, and recognized a corresponding facility lease obligation of $58.2 million. We also recognized, as an additional facility lease obligation, reimbursements totaling $23.6 million from our landlord during 2009 for tenant improvement costs that we incurred since, under FASB authoritative guidance, these reimbursements 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%. At December 31, 2009 and 2008, the facility lease obligation balance in connection with these new facilities was $81.0 million and $54.2 million, respectively.

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In addition, as described above, we amended our lease in December 2009 to include additional new laboratory and office space in Building C that is under construction. As of December 31, 2009, we capitalized $27.8 million of our landlord's costs of constructing these new facilities, and recognized a corresponding facility lease obligation of $27.8 million. Monthly lease payments on these facilities will commence in January 2011 and additional charges for utilities, taxes, and operating expenses commenced in January 2010. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2009 and is recorded as a deferred liability until lease payments commence in January 2011. In addition, interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2009, the facility lease obligation balance in connection with these additional new facilities was $28.0 million.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $97.3 million in 2009, $34.9 million in 2008, and $18.4 million in 2007. As described above, $23.6 million of tenant improvement costs we incurred in Tarrytown were reimbursed by our landlord in 2009. We expect to incur capital expenditures of approximately $80 to $110 million in 2010 and approximately $40 to $60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our newly leased Tarrytown facilities in Building C. In February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. We also expect to be reimbursed for a portion of the capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements

Our total expenses for research and development from inception through December 31, 2009 have been approximately $2.0 billion. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements, such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene®* technology platform. We incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost sharing of a collaborator's development expenses, where applicable, of $333.7 million, $230.6 million, and $108.2 million in 2009, 2008, and 2007, respectively.

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the preclinical and clinical development of product candidates, including rilonacept, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and early preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2009. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

	Payments Due by Period				
	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
			(In millions)		
Operating leases[1]	$ 96.2	$ 6.3	$11.6	$12.4	$ 65.9
Purchase obligations[2]	150.6	112.5	38.1		
Other long-term liabilities[3]	205.4	8.2	22.4	26.6	148.2
Total contractual obligations	$452.2	$127.0	$72.1	$39.0	$214.1

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(1) Excludes future contingent costs for utilities, real estate taxes, and operating expenses included in our rent. In 2009, these costs were $8.4 million. See Note 11(a) to our Financial Statements.

(2) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

(3) Represents payments with respect to facility lease obligations in connection with our lease of facilities in Tarrytown, New York, as described above. See Note 11(a) to our Financial Statements.

As described above, in February 2010, we received $47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. As a result, total contractual obligations, as detailed in the table above, will increase (i) from 127.0 million to $130.9 million for the year ending December 31, 2010, (ii) from $72.1 million to $80.0 million for the two-year period beginning January 1, 2011, (iii) from $39.0 million to $47.0 million for the two-year period beginning January 1, 2013, and (iv) from $214.1 million to $251.6 million for the fiscal years beginning January 1, 2015 and thereafter.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and VEGF Trap-Eye in collaboration with Bayer HealthCare) such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® (rilonacept) for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that

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could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than our operating leases and 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 December 31, 2009, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In 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 prices to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We are required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. We are currently evaluating the impact that this guidance will have on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a $0.6 million and $1.9 million decrease in the fair value of our investment portfolio at December 31, 2009 and 2008, respectively.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of $0.1 million, $2.5 million, and $5.9 million in 2009, 2008, and 2007, respectively.

The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-35 of this report. The supplementary financial information required by this Item is included at page F-35 of this report.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. 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 the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation our management has concluded that our internal control over financial reporting was effective as of December 31, 2009. The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

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 December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors, and employees. The full text of our code of business conduct and ethics can be found on the Company's website *(http://www.regeneron.com)* under the "Corporate Governance" heading on the "About Us" page.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2010 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.

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3. Exhibits

Exhibit Number			Description
3.1	(o)	-	Restated Certificate of Incorporation.
3.2	(a)	-	By-Laws, as amended.
10.1 +	(b)	-	1990 Amended and Restated Long-Term Incentive Plan.
10.2 +	(p)	-	Amended and Restated 2000 Long-Term Incentive Plan.
10.2.1 +	(c)	-	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.2.2 +	(c)	-	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.2.3 +	(d)	-	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.2.4 +	(d)	-	Form of option agreement and related notice of grant for use in connection with the grant of stock options to certain of the Registrant's executive officers in connection with a January 2005 Option Exchange Program.
10.2.5 +	(t)	-	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers.
10.2.6 +	(t)	-	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers.
10.3 +	(s)	-	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
10.4* +	(e)	-	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.5 +	(s)	-	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.6*	(f)	-	IL-1 License Agreement, dated June 26, 2002, by and among the Registrant, Immunex Corporation, and Amgen Inc.
10.7*	(u)	-	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.8*	(u)	-	Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009.
10.9*	(g)	-	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.9.1*	(e)	-	Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 31, 2004.
10.9.2	(h)	-	Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7, 2005.
10.9.3*	(i)	-	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 21, 2005.
10.9.4*	(i)	-	Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and the Registrant, effective as of January 31, 2006.
10.10*	(j)	-	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant.
10.11*	(k)	-	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007, by and between AstraZeneca UK Limited and the Registrant.
10.12	(l)	-	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant.
10.12.1*	(n)	-	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.

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10.12.2	(r)	-	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.12.3	(t)	-	Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.12.4	(v)	-	Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009.
10.12.5	(w)	-	Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10.13*	(m)	-	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant.
10.14*		-	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.15*		-	Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord, and the Registrant.
10.16	(o)	-	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC, and the Registrant.
10.17	(o)	-	Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.17.1		-	First Amendment to the December 20, 2007 Investor Agreement, dated as of November 10, 2009, by and among sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.18*	(q)	-	Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and the Registrant.
23.1		-	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1		-	Power of Attorney (included on the signature page of this Annual Report on Form 10-K)
31.1		-	Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2		-	Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32		-	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

(b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).

(c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.

(d) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.

(e) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2004, filed March 11, 2005.

(f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2002, filed August 13, 2002.

(g) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2003, filed November 12, 2003.

(h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2005, filed February 28, 2006.

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(j) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.

(k) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2006, filed March 12, 2007.

(l) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.

(m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.

(n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.

(o) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.

(p) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed June 17, 2008.

(q) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008.

(r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008.

(s) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009.

(t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009.

(u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009.

(v) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009.

(w) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.

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* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

\+ Indicates a management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

BY: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Dated: Tarrytown, New York
February 18, 2010

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title
/s/ LEONARD S. SCHLEIFER, Leonard S. Schleifer, M.D., Ph.D.	*President, Chief Executive Officer, and Director (Principal Executive Officer)*
/s/ MURRAY A. GOLDBERG Murray A. Goldberg	*Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)*
/s/ DOUGLAS S. MCCORKLE Douglas S. McCorkle	*Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)*
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	*Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director*
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	*Chairman of the Board*
/s/ CHARLES A. BAKER Charles A. Baker	*Director*
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	*Director*
/s/ ALFRED G. GILMAN Alfred G. Gilman, M.D., Ph.D.	*Director*
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	*Director*
/s/ ARTHUR F. RYAN Arthur F. Ryan	*Director*
/s/ ERIC M. SHOOTER Eric M. Shooter, Ph.D.	*Director*
/s/ GEORGE L. SING George L. Sing	*Director*

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REGENERON PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

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Statements of Stockholders' Equity for the years ended December 31, 2009, 2008, and 2007	F-5
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2009 and December 31, 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

New York, New York
February 18, 2010

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REGENERON PHARMACEUTICALS, INC.
BALANCE SHEETS

December 31, 2009 and 2008
(In thousands, except share data)

	2009	2008 *(Revised - see Note 11)*
ASSETS		
Current assets		
Cash and cash equivalents	$ 207,075	$ 247,796
Marketable securities	134,255	226,954
Accounts receivable from the sanofi-aventis Group	62,703	33,302
Accounts receivable - other	2,865	1,910
Prepaid expenses and other current assets	18,610	11,480
Total current assets	425,508	521,442
Restricted cash	1,600	1,650
Marketable securities	47,080	51,061
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	259,676	142,035
Other assets	7,338	8,032
Total assets	$ 741,202	$ 724,220
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 49,031	$ 36,168
Deferred revenue from sanofi-aventis, current portion	17,523	21,390
Deferred revenue - other, current portion	27,021	26,114
Total current liabilities	93,575	83,672
Deferred revenue from sanofi-aventis	90,933	105,586
Deferred revenue - other	46,951	56,835
Facility lease obligations	109,022	54,182
Other long term liabilities	3,959	2,431
Total liabilities	344,440	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 - 2,244,698 in 2009 and 2,248,698 in 2008	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 78,860,862 in 2009 and 77,642,203 in 2008	79	78
Additional paid-in capital	1,336,732	1,294,813
Accumulated deficit	(941,095)	(873,265)
Accumulated other comprehensive income (loss)	1,044	(114)
Total stockholders' equity	396,762	421,514
Total liabilities and stockholders' equity	$ 741,202	$ 724,220

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

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REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2009, 2008, and 2007

(In thousands except share data)

	2009	2008 *(Revised - see Note 11)*	2007 *(Revised - see Note 11)*
Revenues			
Sanofi-aventis collaboration revenue	$247,140	$153,972	$ 51,687
Other collaboration revenue	67,317	31,166	35,961
Technology licensing	40,013	40,000	28,421
Net product sales	18,364	6,249	
Contract research and other	6,434	7,070	8,955
	379,268	238,457	125,024
Expenses			
Research and development	398,762	274,903	202,468
Selling, general, and admistrative	52,923	48,880	37,929
Cost of goods sold	1,686	923	
	453,371	324,706	240,397
Loss from operations	(74,103)	(86,249)	(115,373)
Other income (expense)			
Investment income	4,488	18,161	20,897
Interest expense	(2,337)	(7,752)	(12,043)
Loss on early extinguishment of debt		(938)	
	2,151	9,471	8,854
Net loss before income tax expense	(71,952)	(76,778)	(106,519)
Income tax (benefit) expense	(4,122)	2,351	
Net loss	$ (67,830)	$ (79,129)	$(106,519)
Net loss per share, basic and diluted	$ (0.85)	$ (1.00)	$ (1.61)
Weighted average shares outstanding, basic and diluted	79,782	78,827	66,334

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

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REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2009, 2008, and 2007
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
Balance, December 31, 2006	2,270	$ 2	63,131	$63	$ 904,407	$(687,617)	$ (231)	$ 216,624	
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			886	1	7,618			7,619	
Issuance of Common Stock to sanofi-aventis			12,000	12	311,988			312,000	
Cost associated with issuance of equity securities to sanofi-aventis					(219)			(219)	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			65		1,367			1,367	
Issuance of restricted Common Stock under Long- Term Incentive Plan			500	1	(1)				
Conversion of Class A Stock to Common Stock	(10)		10						
Stock-based compensation expense					28,075			28,075	
Net loss, 2007						(106,519)		(106,519)	$(106,519)
Change in net unrealized gain (loss) on marketable securities							401	401	401
Balance, December 31, 2007 ***(Revised- see Note 11)***	2,260	2	76,592	77	1,253,235	(794,136)	170	459,348	$(106,118)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			980	1	7,948			7,949	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			59		1,107			1,107	
Conversion of Class A Stock to Common Stock	(11)		11						
Stock-based compensation expense					32,523			32,523	
Net loss, 2008						(79,129)		(79,129)	$ (79,129)
Change in net unrealized gain (loss) on marketable securities							(284)	(284)	(284)
Balance, December 31, 2008 ***(Revised - see Note 11)***	2,249	2	77,642	78	1,294,813	(873,265)	(114)	421,514	$ (79,413)
Issuance of Common Stock in connection with exercise of stock options, net of shares tendered			1,134	1	9,269			9,270	
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	(4)		4						
Stock-based compensation expense					31,259			31,259	
Net loss, 2009						(67,830)		(67,830)	$ (67,830)
Change in net unrealized gain (loss) on marketable securities, net of tax effect of $0.7 million							1,158	1,158	1,158
Balance, December 31, 2009	2,245	$ 2	78,861	$79	$1,336,732	$(941,095)	$1,044	$ 396,762	$ (66,672)

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

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REGENERON PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2009, 2008, and 2007

	2009	2008	2007
		(In thousands)	
Cash flows from operating activities			
Net loss	$ (67,830)	$ (79,129)	$(106,519)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	14,247	11,287	11,487
Non-cash compensation expense	31,259	32,523	28,075
Other non-cash expenses	(382)		
Loss on early extinguishment of debt		938	
Net realized (gain) loss on marketable securities	(56)	1,310	5,943
Changes in assets and liabilities			
Increase in accounts receivable	(30,356)	(16,892)	(10,827)
Increase in prepaid expenses and other assets	(4,574)	(6,560)	(9,649)
(Decrease) increase in deferred revenue	(27,497)	(26,834)	89,764
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	12,959	(5,729)	19,098
Total adjustments	(4,400)	(9,957)	133,891
Net cash (used in) provided by operating activities	(72,230)	(89,086)	27,372
Cash flows from investing activities			
Purchases of marketable securities	(199,997)	(581,139)	(594,446)
Sales or maturities of marketable securities	297,411	646,861	527,169
Capital expenditures	(97,318)	(34,857)	(18,446)
Decrease (increase) in restricted cash	50	(50)	
Net cash provided by (used in) investing activities	146	30,815	(85,723)
Cash flows from financing activities			
Repurchases or repayment of notes payable		(200,807)	
Proceeds in connection with facility lease obligation	23,640		
Payments in connection with facility lease obligation	(875)		
Net proceeds from the issuance of Common Stock	8,598	7,949	319,400
Net cash provided by (used in) financing activities	31,363	(192,858)	319,400
Net (decrease) increase in cash and cash equivalents	(40,721)	(251,129)	261,049
Cash and cash equivalents at beginning of period	247,796	498,925	237,876
Cash and cash equivalents at end of period	$ 207,075	$ 247,796	$ 498,925
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 2,525	$ 9,348	$ 11,000
Cash paid for income taxes		$ 3,079	

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

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1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of therapeutics to treat human disorders and conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for the Company's first commercial drug product, ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company's facilities are primarily located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company has invested its excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities, and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. The Company considers its marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets 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 marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that may be charged against income. As described under "Use of Estimates" below, 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.

Capitalization of Inventory Costs

The Company does not capitalize inventory costs associated with commercial supplies of drug product until it has received marketing approval from the FDA. Prior to receipt of FDA approval, costs for manufacturing supplies of drug product are recognized as research and development expenses in the period that the costs were incurred. Therefore, these pre-approval manufacturing costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of drug product.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	7-35 years
Laboratory and other equipment	3-10 years
Furniture and fixtures	5 years

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Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term, without assuming renewal features, if any, are exercised. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company has obtained, applied for, or is applying for, a number of patents to protect proprietary technology and inventions. All costs associated with patents for product candidates under development are expensed as incurred. Patent costs related to commercial products are capitalized and amortized over the remaining patent term. To date, the Company has no capitalized patent costs.

Operating Leases

On certain of its operating lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes operating lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. In addition, lease incentives that the Company receives are treated as a reduction of rent expense over the term of the related agreements.

Revenue Recognition

Certain reclassifications have been made to our prior year revenue amounts to conform to the 2009 presentation.

a. Collaboration Revenue

The Company earns collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer

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HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as collaboration revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of the collaborator's development expenses that the Company is obligated to reimburse.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays, or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. For example, during the fourth quarter of 2008, the Company extended its estimated performance period in connection with the up-front and non-substantive milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened its estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in the Company's estimates resulted in the recognition of $0.4 million less in collaboration revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. In addition, in connection with amendments to expand and extend the Company's antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, the Company extended its estimated performance period related to the up-front payment previously received from sanofi-aventis pursuant to the companies' antibody collaboration. The effect of this change in estimate resulted in the recognition of $0.6 million less in collaboration revenue in the fourth quarter of 2009, compared to amounts recognized in each of the prior three quarters of 2009. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

b. *VelocImmune*® Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune* technology in its internal research programs. The terms of these agreements include annual, non-refundable payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune* technology. Annual, non-refundable payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

c. Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related costs. Since the Company currently has limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or the Company can reasonably

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estimate returns and (ii) rebates have been processed or the Company can reasonably estimate rebates. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues expense on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

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Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's Long-Term Incentive Plans, to employees and non-employee members of the Company's board of directors, based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, the Company has granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, the Company estimates that these options will vest, which is based on whether the Company consider the options' performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain.

Uncertain tax positions are accounted for in accordance with FASB authoritative guidance, which the Company adopted on January 1, 2007. Such guidance prescribes a comprehensive model for the manner in which a company should recognize, measure, present, and disclose in its financial statements all material uncertain tax positions that the company has taken or expects to take on a tax return. Those positions, for which management's assessment is that there is more than a 50% probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to certain measurement criteria. For the years ended December 31, 2009, 2008, and 2007, the Company has not recognized any income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed by FASB authoritative guidance.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense.

Comprehensive Income (Loss)

Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities, net of any tax effect. Comprehensive income (loss) for the years ended December 31, 2009, 2008, and 2007 have been included in the Statements of Stockholders' Equity.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 6), and receivables from sanofi-aventis.

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Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2009, 2008, and 2007 does not include common stock equivalents, since such inclusion would be antidilutive.

Risks and Uncertainties

Developing and commercializing new medicines entails significant risk and expense. Since its inception, the Company has not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of the Company's other product candidates. Before revenues from the commercialization of the Company's current or future product candidates can be realized, the Company (or its 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 the Company's products and technologies uncompetitive or obsolete. The Company may be subject to legal claims by third parties seeking to enforce patents to limit or prohibit the Company from marketing or selling its products. The Company is also dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST product sales, and (iv) investment income. Collaboration revenue in 2009 was earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 3 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include:

- Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.
- Product rebates and returns in connection with the recognition of revenue from product sales.
- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.

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- In connection with stock option awards, (i) the fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives; (ii) the number of stock option awards that are expected to be forfeited; and (iii) with respect to performance-based stock option awards, if and when we consider the options' performance conditions to be probable of attainment.
- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.
- Useful lives of property, plant, and equipment.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

In addition, the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter, are included in research and development expenses. The Bayer HealthCare estimate for the most recent fiscal quarter is adjusted in the subsequent quarter to reflect actual expenses for the quarter.

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 prices 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.

3. Collaboration and Contract Research Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements totaled $320.9 million, $192.2 million, and $96.6 million in 2009, 2008, and 2007, respectively. Total Company-incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were $333.7 million, $230.6 million, and $108.2 million in 2009, 2008, and 2007, respectively. Significant agreements of this kind are described below.

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a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aflibercept Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofi-aventis made a non-refundable up-front payment of $80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for $45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aflibercept Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a $25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment").

In December 2005, the Company and sanofi-aventis amended the Aflibercept Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a $25.0 million non-refundable up-front payment to the Company, which was received in January 2006. Under the Aflibercept Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to $400 million in milestone payments upon receipt of specified marketing approvals, including up to $360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to $40 million related to the receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aflibercept 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, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of $598.4 million as of December 31, 2009, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aflibercept Agreement, the Intraocular Termination Payment of $25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to $7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

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

In accordance with the Company's revenue recognition policy described in Note 2, the up-front payments received in September 2003 and January 2006, of $80.0 million and $25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as collaboration revenue over the related performance period. The Company recognized $36.5 million, $44.4 million, and $47.1 million of collaboration development revenue in 2009, 2008, and 2007, respectively, in connection with the Aflibercept Agreement, as amended. At December 31, 2009 and 2008, amounts receivable from sanofi-aventis totaled $3.6 million and $6.3 million, respectively, and deferred revenue was $42.5 million and $52.4 million, respectively, in connection with the Aflibercept Agreement.

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Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for $312.0 million (see Note 12).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable up-front payment of $85.0 million from sanofi-aventis under the Discovery Agreement. In addition, under the Discovery Agreement, sanofi-aventis funded $174.5 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against those targets from the collaboration's inception through December 31, 2009. In November 2009, the Company and sanofi-aventis amended these collaboration agreements to expand and extend the Antibody Collaboration. Pursuant to the Discovery Agreement, as amended, sanofi-aventis will fund up to $160 million per year of the Company's research activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to $120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. The amended Discovery Agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

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 the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The Company and sanofi-aventis are currently co-developing five therapeutic antibodies under the License Agreement.

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") will be shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of $140.2 million as of December 31, 2009) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products. However, the Company is not required to apply more than 10% of its share of the profits from the antibody collaboration in any calendar quarter to reimburse sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's 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% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's Discovery Agreement, sanofi-aventis will fund up to $30 million of agreed-upon costs incurred by the Company to expand its manufacturing capacity at the Company's Rensselaer, New York facilities.

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With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, sanofi-aventis has the right to terminate the Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the Discovery Agreement, sanofi-aventis has an option to license the Company's *VelocImmune®* technology for agreed upon consideration.

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with sanofi-aventis to use Regeneron's proprietary *VelociGene®* technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease (the "*VelociGene* Agreement"). The VelociGene Agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which the Company expects to receive payments totaling a minimum of $21.5 million.

In accordance with the Company's revenue recognition policy described in Note 2, the (i) $85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, (iii) $21.5 million of aggregate minimum payments under the *VelociGene* Agreement, and (iv) reimbursement of agreed-upon costs to expand the Company's manufacturing capacity are being recognized as collaboration revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized $210.7 million, $109.6 million, and $4.6 million of collaboration revenue in 2009, 2008, and 2007, respectively. In addition, at December 31, 2009 and 2008, amounts receivable from sanofi-aventis totaled $59.1 million and $27.0 million and deferred revenue was $66.0 million and $74.6 million, respectively.

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of $75.0 million. In August 2007, the Company received a $20.0 million milestone payment from Bayer HealthCare (which, for the purpose of revenue recognition, was not considered substantive) following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). In July 2009, the Company 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 Central Retinal Vein Occlusion ("CRVO"). In addition, the Company is eligible to receive up to $70 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. The Company is also eligible to receive up to $135 million in sales milestones when and if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at $200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of $138.4 million as of December 31, 2009) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of VEGF Trap-Eye and retains exclusive rights to any future profits from such commercialization in the United States.

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Agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 and 2008 under a global development plan, were shared as follows:

2007: The first $50.0 million was shared equally and the Company was solely responsible for up to the next $40.0 million.

2008: The first $70.0 million was shared equally and the Company was solely responsible for up to the next $30.0 million.

In 2009 and thereafter, all development expenses will be shared equally. Neither party was reimbursed for any development expenses that it incurred prior to 2007. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

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

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer HealthCare reaffirmed the companies' commitment to a diabetic macular edema ("DME") development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses. The $75.0 million up-front licensing payment and the $20.0 million milestone payment received in August 2007 from Bayer HealthCare are being recognized as collaboration revenue over the related estimated performance period in accordance with the Company's revenue recognition policy as described in Note 2. In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse. In the fourth quarter of 2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

The Company recognized $67.3 million, $31.2 million, and $35.9 million of collaboration revenue from Bayer HealthCare in 2009, 2008, and 2007, respectively. In 2009, collaboration revenue from Bayer HealthCare included the $20.0 million milestone payment received in July 2009 which, for the purpose of revenue recognition, was considered substantive. In addition, in 2009, 2008, and 2007, the Company recognized as additional research and development expense $37.7 million, $30.0 million, and $10.6 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

In connection with cost-sharing of VEGF Trap-Eye expenses under the collaboration, $1.2 million and $9.8 million was payable to Bayer HealthCare at December 31, 2009 and 2008, respectively. In addition, at December 31, 2009 and 2008, deferred revenue from the Company's collaboration with Bayer HealthCare was $56.8 million and $66.7 million, respectively.

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c. National Institute of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. As amended, the NIH grant provides a minimum of $25.3 million in funding over a five-year period, including $1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene®* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. The Company records revenue in connection with the NIH grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals. In 2009, 2008, and 2007, the Company recognized contract research revenue of $5.5 million, $4.9 million, and $5.5 million, respectively, from the NIH Grant.

4. Technology Licensing Agreements

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a $20.0 million annual, non-refundable payment to the Company in each of 2009, 2008, and 2007. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. AstraZeneca is required to make up to three additional annual payments of $20.0 million, subject to their ability to terminate the agreement after making the next annual payment in 2010. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the years ended December 31, 2009, 2008, and 2007, the Company recognized $20.0 million, $20.0 million, and $17.1 million of technology licensing revenue. In addition, deferred revenue at December 31, 2009, 2008, and 2007 was $2.9 million.

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to the Company in each of 2009, 2008, and 2007. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. Astellas is required to make up to three additional annual payments of $20.0 million, subject to their ability to terminate the agreement after making the next annual payment in 2010. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune* technology. In connection with the Astellas license agreement, for the years ended December 31, 2009, 2008, and 2007, the Company recognized $20.0 million, $20.0 million, and $11.3 million of technology licensing revenue. In addition, deferred revenue at December 31, 2009, 2008, and 2007 was $8.7 million.

5. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the years-ended December 31, 2009 and 2008, the Company recognized as revenue $18.4 million and $6.3 million, respectively, of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $4.8 million and $4.0 million, respectively.

Cost of goods sold related to ARCALYST sales totaled $1.7 million and $0.9 million for the years ended December 31, 2009 and 2008, respectively, and consisted primarily of royalties (see Note 11b). 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 December 31, 2009, the Company had $0.4 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

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6. Marketable Securities

Marketable securities at December 31, 2009 and 2008 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was $5.5 million and $3.7 million at December 31, 2009 and 2008, respectively, and the aggregate cost basis of which was $4.0 million and $4.1 million at December 31, 2009 and 2008, respectively. 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 December 31, 2009 and 2008. The Company classifies its debt securities, other than mortgage-backed and other asset-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed and other asset-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair	Unrealized Holding		
At December 31, 2009	**Cost Basis**	**Value**	**Gains**	**(Losses)**	**Net**
Maturities within one year					
U.S. government obligations	$100,491	$100,573	$ 82		$ 82
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10,142	10,342	200		200
Mortgage-backed securities	2,471	2,338		$ (133)	(133)
U.S. government guaranteed collateralized mortgage obligations	3,612	3,662	50		50
	133,892	134,255	496	(133)	363
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	31,344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,645	41,611	280	(314)	(34)
	$175,537	$175,866	$ 776	$ (447)	$ 329
At December 31, 2008					
Maturities within one year					
U.S. government obligations	$170,993	$172,253	$1,260		$1,260
Corporate bonds	26,894	26,662	25	$ (257)	(232)
Mortgage-backed securities	9,098	8,420		(678)	(678)
Other asset-backed securities	7,842	7,829		(13)	(13)
U.S. government guaranteed collateralized mortgage obligations	11,742	11,792	50		50
	226,569	226,956	1,335	(948)	387
Maturities between one and three years					
U.S. government guaranteed corporate bonds	29,853	29,811	82	(124)	(42)
Corporate bonds	10,446	10,414	77	(109)	(32)
Mortgage-backed securities	1,821	1,556		(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	5,297	5,570	273		273
	47,417	47,351	432	(498)	(66)
	$273,986	$274,307	$1,767	$(1,446)	$ 321

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At December 31, 2009 and 2008, marketable securities included an additional unrealized gain of $1.4 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 December 31, 2009 and 2008. The debt securities listed at December 31, 2009 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		Total	
At December 31, 2009	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. government obligations	$ 9,367	$ (46)			$ 9,367	$ (46)
Mortgage-backed securities			3,238	(401)	3,238	(401)
	$ 9,367	$ (46)	$ 3,238	$(401)	$12,605	$ (447)
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 the years ended December 31, 2009 and 2008, realized gains on sales of marketable securities totaled $0.2 million and $1.2 million, respectively, and realized losses on sales of marketable securities were not significant. For the year ended December 31, 2007, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at December 31, 2009 and 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
Description	Fair Value at December 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale marketable securities				
U.S. government obligations	$109,940		$109,940	
U.S. government guaranteed corporate bonds	48,684		48,684	
Corporate bonds	10,342		10,342	
Mortgage-backed securities	3,238		3,238	
U.S. government guaranteed collateralized mortgage obligations	3,662		3,662	
Equity securities	5,469	5,469		
Total	$181,335	$5,469	$175,866	

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Description	Fair Value at December 31, 2008	Fair Value Measurements at Reporting Date Using: 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 fair value for these securities. During the years ended December 31, 2009 and 2007, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities. During the year ended December 31, 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 $1.8 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 year ended December 31, 2007, deterioration in the credit quality of marketable securities from two issuers subjected the Company to the risk of not being able to recover the full principal value of these securities. As a result, the Company recognized a $5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. During the years ended December 31, 2009 and 2008, the Company recognized an additional $0.1 million and $0.7 million, respectively, in other-than-temporary impairment charges related to one of these marketable securities.

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the years ended December 31, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the years ended December 31, 2009 and 2008.

Changes in marketable securities included in Level 3 during the years ended December 31, 2009 and 2008 were as follows:

	Level 3 Marketable Securities	
	2009	2008
Balance, January 1	$ 100	$ 7,950
Settlements		(8,194)
Realized gain		1,044
Impairments	(100)	(700)
Balance, December 31	$	$ 100

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As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment and the deterioration in the credit quality of issuers of securities that the Company holds increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

7. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Land	$ 2,117	$ 2,117
Building and improvements	177,710	74,343
Leasehold improvements	4,023	2,720
Construction-in-progress	58,541	78,702
Laboratory and other equipment	114,099	75,935
Furniture, computer and office equipment, and other	15,964	7,501
	372,454	241,318
Less, accumulated depreciation and amortization	(112,778)	(99,283)
	$ 259,676	$ 142,035

Building and improvements at December 31, 2009 includes $58.2 million of costs incurred by the Company's landlord to construct new laboratory and office facilities in Tarrytown, New York in connection with the Company's December 2006 lease, as amended, of these new facilities. In addition, construction-in-progress at December 31, 2009 and 2008 includes $27.8 million and $54.2 million, respectively, of costs incurred by the Company's landlord in connection with these new facilities. See Note 11a.

The Company capitalized interest costs of $0.5 million in 2009. The Company did not capitalize any interest costs in 2008 or 2007.

Depreciation and amortization expense on property, plant, and equipment amounted to $14.2 million, $10.6 million, and $10.4 million for the years ended December 31, 2009, 2008, and 2007, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Accounts payable	$18,638	$ 6,268
Payable to Bayer HealthCare	1,186	9,799
Accrued payroll and related costs	9,444	5,948
Accrued clinical trial expense	11,673	4,273
Accrued property, plant, and equipment expenses	1,883	5,994
Accrued expenses, other	6,207	3,886
	$49,031	$36,168

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9. Deferred Revenue

Deferred revenue as of December 31, 2009 and 2008 consists of the following:

	2009	2008
Current portion:		
Received from sanofi-aventis (see Note 3a)	$ 17,523	$ 21,390
Received from Bayer HealthCare (see Note 3b)	9,884	9,884
Received for technology license agreements (see Note 4)	11,579	11,579
Other	5,558	4,651
	$ 44,544	$ 47,504
Long-term portion:		
Received from sanofi-aventis (see Note 3a)	$ 90,933	$105,586
Received from Bayer HealthCare (see Note 3b)	46,951	56,835
	$137,884	$162,421

10. Convertible Debt

In October 2001, the Company issued $200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of $192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bore interest at 5.5% per annum, payable semi-annually, and matured on October 17, 2008. Deferred Financing Costs, which were included in other assets, were amortized as interest expense over the period from the Notes' issuance to stated maturity. During the second and third quarters of 2008, the Company repurchased $82.5 million in principal amount of the Notes for $83.3 million and recognized a $0.9 million loss on early extinguishment of debt, representing the premium paid on the Notes plus related unamortized Deferred Financing Costs. The remaining $117.5 million of outstanding Notes were repaid in full upon their maturity in October 2008.

11. Commitments and Contingencies

a. Leases

Descriptions of Lease Agreements

The Company leases laboratory and office facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended (the "Tarrytown Lease"). The facilities leased by the Company under the Tarrytown Lease include (i) space in previously existing buildings, (ii) newly constructed space in two new buildings ("Buildings A and B") that was completed during the third quarter of 2009 and, (iii) under a December 2009 amendment to the Tarrytown Lease, additional new space that is under construction in a third new building ("Building C"), which is expected to be completed in mid-2011. The Tarrytown Lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, as well as early termination options for various portions of the space exclusive of the newly constructed space in Buildings A and B. The Tarrytown Lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the Tarrytown Lease are accounted for as operating leases. However, for the newly constructed space that the Company is leasing, the Company is deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance, and the landlord's costs of constructing these new facilities are 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.

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In connection with the Tarrytown Lease, at lease inception, the Company issued a letter of credit in the amount of $1.6 million to its landlord, which is collateralized by a $1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2009 and 2008.

In October 2008, the Company entered into a sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commenced in January 2009 and expires in July 2011. The Company also formerly leased additional office space in Tarrytown, New York under operating subleases that ended at various times through September 2009.

The Company formerly leased manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement. The lease provided for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined. In June 2007, the Company exercised a purchase option under the lease and, in October 2007, purchased the land and building.

The Company also leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

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 Tarrytown Lease of new laboratory and office facilities in Buildings A and B. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

The Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities.

As previously disclosed in the Company's Quarterly Reports on Form 10-Q for the quarters ended June 30 and September 30, 2009, 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, 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.

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For comparative purposes, the impact of the above described revisions to the Company's balance sheet as of December 31, 2008 is as follows:

Balance Sheet Impact at December 31, 2008
(in millions)

	December 31, 2008
As originally reported	
Property, plant, and equipment, net	$ 87.9
Total assets	670.0
Other long-term liabilities	5.1
Total liabilities	251.2
Accumulated deficit	(875.9)
Total stockholders' equity	418.8
Total liabilities and stockholders' equity	670.0
As revised	
Property, plant, and equipment, net	$ 142.0
Total assets	724.2
Facility lease obligation	54.2
Other long-term liabilities	2.4
Total liabilities	302.7
Accumulated deficit	(873.3)
Total stockholders' equity	421.5
Total liabilities and stockholders' equity	724.2

For comparative purposes, the impact of the above described revisions to the Company's statements of operations for the period(s) set forth below is as follows:

Statements of Operations Impact for the years ended December 31, 2008 and 2007
(in millions, except per share data)

	December 31,	
	2008	2007
As originally reported		
Research and development expenses	$278.0	$ 201.6
Selling, general, and administrative expenses	49.3	37.9
Total expenses	328.3	239.5
Net loss	(82.7)	(105.6)
Net loss per share, basic and diluted	$ (1.05)	$ (1.59)
As revised		
Research and development expenses	$274.9	$ 202.5
Selling, general, and administrative expenses	48.9	37.9
Total expenses	324.7	240.4
Net loss	(79.1)	(106.5)
Net loss per share, basic and diluted	$ (1.00)	$ (1.61)

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These revised amounts are reflected in the Company's financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2009.

Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2010	$ 5,919	$387	$ 6,306
2011	6,336	160	6,496
2012	5,020	48	5,068
2013	6,159	2	6,161
2014	6,262		6,262
Thereafter	65,883		65,883
	$95,579	$597	$96,176

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2009	$7,722	$395	$8,117
2008	6,530	416	6,946
2007	5,551	363	5,914

In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of $8.4 million, $8.4 million, and $8.8 million for the years ended December 31, 2009, 2008, and 2007, respectively.

Facility Lease Obligations

As described above, in connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Buildings A and B, the Company capitalized the landlord's costs of constructing the new facilities, which totaled $58.2 million as of December 31, 2009, and recognized a corresponding facility lease obligation of $58.2 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling $23.6 million from the Company's landlord during 2009 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 year ended December 31, 2009, the Company recognized in its statement of operations $2.3 million of interest expense in connection with the facility lease obligation. At December 31, 2009 and 2008, the facility lease obligation balance in connection with these new facilities was $81.0 million and $54.2 million, respectively.

In addition, as described above, in December 2009, the Company amended its December 2006 agreement to lease additional new laboratory and office facilities in Building C that is under construction. In connection with the application of FASB authoritative guidance to the Company's lease of these additional new facilities, the Company is deemed, in substance, to be the owner of the landlord's building, and the landlord's costs of constructing these new facilities is 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. As of December 31, 2009, the Company capitalized $27.8 million of the landlord's costs of constructing the new facilities, and recognized a corresponding facility lease obligation of $27.8 million. Monthly lease payments on these facilities will commence in January 2011. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2009 and is recorded as a deferred liability until lease payments commence in January 2011. In addition,

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interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2009, the facility lease obligation balance in connection with these additional new facilities was $28.0 million.

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2009, were as follows:

December 31,	Buildings A and B	Building C	Total
2010	$ 8,152		$ 8,152
2011	8,381	$ 2,675	11,056
2012	8,616	2,753	11,369
2013	8,856	4,270	13,126
2014	9,103	4,389	13,492
Thereafter	99,981	48,172	148,153
	$143,089	$62,259	$205,348

In February 2010, the Company received $47.5 million from the Company's landlord in connection with tenant improvement costs for Buildings A, B, and C. As a result, future minimum noncancellable commitments under facility lease obligations, as detailed in the table above, will increase by $3.9 million in each of the five years from 2010 to 2014 and $37.5 million for the years thereafter.

b. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of $2.8 million, $3.5 million, and $1.0 million for the years ended December 31, 2009, 2008, and 2007, respectively.

In connection with the Company's receipt of marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST net product sales. For the years ended December 31, 2009 and 2008, ARCALYST royalties totaled $1.5 million and $0.6 million, respectively, and are included in cost of goods sold.

In July 2008, the Company and Cellectis S.A. ("Cellectis") entered into an Amended and Restated Non-Exclusive License Agreement (the "Cellectis Agreement"). The Cellectis Agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which the Company licensed certain patents and patent applications from Cellectis. Pursuant to the Cellectis Agreement, in July 2008, the Company made a non-refundable $12.5 million payment to Cellectis (the "Cellectis Payment") and agreed to pay Cellectis a low single-digit royalty based on revenue received by the Company from any future licenses or sales of the Company's *VelociGene®* or *VelocImmune®* products and services. No royalties are payable with respect to the Company's *VelocImmune* license agreements with AstraZeneca and Astellas or the Company's antibody collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from the Company's *VelocImmune* technology.

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The Company began amortizing the Cellectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's antibody collaboration with sanofi-aventis (as amended in November 2009). In 2009 and 2008, the Company recognized $2.3 million and $2.7 million, respectively, of expense in connection with the Cellectis Payment. At December 31, 2009 and 2008, the unamortized balance of the Cellectis Payment, which was included in other assets, was $7.6 million and $9.8 million, respectively. The Company estimates that it will recognize expense of $1.1 million in 2010, $1.0 million in 2011, and $0.9 million in each of 2012, 2013, and 2014, in connection with the Cellectis Payment.

12. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 160 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors (the "Board") is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the Board.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for $45.0 million. See Note 3.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of $312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company, which was amended in November 2009. Under the amended investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement under the Company's antibody collaboration with sanofi-aventis (see Note 3) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 3), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Under the amended investor agreement, sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2017, subject to certain limited exceptions. Following December 20, 2017, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of the Company's Common Stock, and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's Board of Directors or proportionally with the votes cast by the Company's 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 the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

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13. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 28,816,184 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and have a term of ten years.

The 1990 and 2000 Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined.

As of December 31, 2009, there were 3,949,767 shares available for future grants under the 2000 Incentive Plan.

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a. Stock Options

Transactions involving stock option awards during 2009 under the 1990 and 2000 Incentive Plans are summarized in the table below.

Stock Options:	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
Outstanding at December 31, 2008	20,133,910	$17.53		
2009: Granted	3,490,560	$20.69		
Forfeited	(390,328)	$19.17		
Expired	(74,589)	$21.46		
Exercised	(1,370,798)	$10.19		
Outstanding at December 31, 2009	21,788,755	$18.45	6.45	$150,472
Vested and expected to vest at December 31, 2009	21,263,460	$18.44	6.39	$147,516
Exercisable at December 31, 2009	12,504,511	$18.18	4.98	$ 96,967

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2009, 2008, and 2007 was $13.2 million, $11.9 million, and $12.6 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the average market price of the Company's Common Stock on the date of grant ("Market Price"). The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2007, 2008, and 2009. The fair value of each option granted under the 2000 Incentive Plan during 2009, 2008, and 2007 was estimated on the date of grant using the Black-Scholes option-pricing model.

	Number of Options Granted	Weighted-Average Exercise Price	Weighted-Average Fair Value
2007:			
Exercise price equal to Market Price	3,415,743	$21.78	$11.13
2008:			
Exercise price equal to Market Price	4,126,600	$17.38	$ 8.45
2009:			
Exercise price equal to Market Price	3,490,560	$20.69	$10.89

For the years ended December 31, 2009, 2008, and 2007, $27.4 million, $30.3 million, and $28.0 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards was recognized in operating expenses. As of December 31, 2009, there was $44.8 million of stock-based compensation cost related to outstanding non-performance based stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.9 years.

In addition, there were 1,939,760 performance-based options which were unvested as of December 31, 2009 of which, subject to the optionee satisfying certain service conditions, 664,760 options that were issued in 2007 would vest upon achieving certain defined sales targets for the Company's products and 1,275,000 options that were issued in 2008 and 2009 would vest upon achieving certain development milestones for the Company's product candidates. In light of the status of the Company's development programs at December 31, 2009, the Company estimates that approximately 850,000 of the performance-based options tied to achieving development milestones will vest since

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the Company considers these options' performance conditions to be probable of attainment. As a result, in 2009, the Company recognized $1.7 million of non-cash stock-based compensation expense related to these performance options. As of December 31, 2009, there was $8.7 million of stock-based compensation cost which had not yet been recognized in operating expenses related to the performance-based options that the Company currently estimates will vest. The Company expects to recognize this compensation cost over a weighted-average period of 2.5 years. In addition, potential compensation cost of $7.7 million related to those performance options whose performance conditions (based on current facts and circumstances) are not currently considered by the Company to be probable of attainment will begin to be recognized only if, and when, the Company estimates that it is probable that these options will vest. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation recognized in future periods related to performance-based options.

Fair value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2009, 2008, and 2007.

	2009	2008	2007
Expected volatility	54%	53%	53%
Expected lives from grant date	5.9 years	5.5 years	5.6 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	2.87%	1.73%	3.60%

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the year ended December 31, 2009 is summarized below:

Restricted Stock:	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2008	500,000	$21.92
Outstanding at December 31, 2009	500,000	$21.92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapses, which is five years for the grant made in 2007. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholders' Equity of $11.0 million, which was combined with additional paid-in capital. The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of $2.2 million, $2.2 million, and $0.1 million in 2009, 2008, and 2007, respectively. As of December 31, 2009, there were 500,000 unvested shares

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of Restricted Stock outstanding and $6.5 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 3 years.

14. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2009, there were 44,246 shares available for future grants under the Plan.

15. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of $2.6 million in 2009, $1.5 million in 2008, and $1.4 million in 2007, and such amounts were accrued as liabilities at December 31, 2009, 2008, and 2007, respectively. During the first quarter of 2010, 2009, and 2008, the Company contributed 111,419, 81,086, and 58,575 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

16. Income Taxes

For the year ended December 31, 2009, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. In 2009, the Company recognized a $4.1 million income tax benefit, consisting of (i) $2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows the Company to claim a refund of U.S. federal alternative minimum tax ("AMT") that the Company paid in connection with its 2007 U.S. federal income tax return, as described below, (ii) $0.7 million income tax benefit resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2009 U.S. federal income tax return, and (iii) $0.7 million income tax benefit in connection with the net tax effect of the Company's unrealized gain on "available-for-sale" marketable securities, which is included in other comprehensive income in 2009.

For the year ended December 31, 2008, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. During 2008, the Company implemented a tax planning strategy to utilize net operating loss carry-forwards (which were otherwise due to expire in 2008 through 2012) on its 2007 U.S. federal and New York State income tax returns that were filed in September 2008. The tax planning strategy included electing, for tax purposes only, to capitalize $142.1 million of 2007 research and development ("R&D") costs and amortize these costs over ten years for tax purposes. By capitalizing these R&D costs, the Company was able to generate taxable income for tax year 2007 and utilize the net operating loss carry-forwards to offset this taxable income. As a result, the Company incurred and paid income tax expense of $3.1 million in 2008, which related to U.S. federal and New York State AMT and included $0.2 million of interest and penalties. This expense was partly offset by the Company's recognition of a $0.7 million income tax benefit in 2008, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2008 U.S federal income tax return.

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For the year ended December 31, 2007, the Company had projected to incur a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2007. Subsequently, the Company implemented the tax planning strategy described above, which resulted in taxable income in 2007 on which the Company recognized and paid U.S. federal and New York State AMT in 2008.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2009 and 2008 is as follows:

	2009	2008
Deferred tax assets:		
Net operating loss carry-forward	$ 200,266	$ 161,790
Fixed assets	13,833	18,612
Deferred revenue	73,865	85,251
Deferred compensation	29,736	22,942
Research and experimental tax credit carry-forward	22,377	22,295
Capitalized research and development costs	49,107	59,661
Other	10,142	9,825
Valuation allowance	(399,326)	(380,376)
	—	—

The Company's valuation allowance increased by $19.0 million in 2009, due primarily to the increase in the net operating loss carry-forward. In 2008, the Company's valuation allowance increased by $37.4 million, due primarily to the increase in the temporary difference related to capitalized research and development costs, resulting from the implementation of the tax planning strategy described above.

The Company is primarily subject to U.S. federal and New York State income tax. The difference between the Company's effective income tax rate and the U.S federal statutory rate of 35% is primarily attributable to an increase in the deferred tax valuation allowance. Due to the Company's history of losses, all tax years remain open to examination by U.S. federal and state tax authorities. As described in Note 2 under "Income Taxes", the implementation of FASB authoritative guidance on January 1, 2007, and for the years ended December 31, 2009, 2008, and 2007, had no impact on the Company's financial statements as the Company has not recognized any income tax positions that were deemed uncertain under the prescribed recognition thresholds and measurement attributes.

As of December 31, 2009 and 2008, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2009, the Company had available for tax purposes unused net operating loss carry-forwards of $516.3 million which will expire in various years from 2018 to 2029 and included $21.7 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental tax credit carry-forwards expire in various years from 2010 to 2029. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

17. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

Samsung Bioepis Exhibit 1012 - Page 5445
Biocon Exhibit 1012 - Page 5445

18. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares 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. In 2009, 2008, and 2007, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2009	2008	2007
Net loss (Numerator)	$(67,830)	$(79,129)	$(106,519)
Weighted-average shares, in thousands (Denominator)	79,782	78,827	66,334
Basic and diluted net loss per share	$ (0.85)	$ (1.00)	$ (1.61)

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

	December 31,		
	2009	2008	2007
Options:			
Weighted average number, in thousands	20,040	17,598	15,385
Weighted average exercise price	$ 17.66	$ 17.31	$ 15.97
Restricted Stock:			
Weighted average number, in thousands	500	500	21
Convertible Debt:			
Weighted average number, in thousands			6,611
Conversion price			$ 30.25

19. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2009, 2008, and 2007 were $9.8 million, $7.0 million, and $1.7 million of accrued capital expenditures, respectively.

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 11a), the Company recognized a facility lease obligation of $31.7 million and $32.6 million during 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, 2007, and 2006 were $1.5 million, $1.1 million, and $1.4 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2009, 2008, and 2007, the Company contributed 81,086, 58,575, and 64,532, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in other assets at December 31, 2009 was $0.7 million due to the Company in connection with employee exercises of stock options in December 2009.

Included in marketable securities at December 31, 2009, 2008, and 2007 were $0.6 million, $1.7 million, and $2.2 million of accrued interest income, respectively.

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20. Subsequent Events

The Company has evaluated subsequent events through February 18, 2010, 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 year ended December 31, 2009. As described in Note 11a under "Facility Lease Obligations," in February 2010, the Company received $47.5 million from the Company's landlord in Tarrytown, New York, in connection with tenant improvement costs.

21. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2009 and 2008 are set forth in the following tables.

	First Quarter Ended March 31, 2009	Second Quarter Ended June 30, 2009	Third Quarter Ended September 30, 2009	Fourth Quarter Ended December 31, 2009
		(Unaudited)		
Revenues	$ 74,981	$ 90,032	$117,455	$ 96,800
Net loss	(15,388)	(14,938)	(1,015)	(36,489)
Net loss per share, basic and diluted:	$ (0.19)	$ (0.19)	$ (0.01)	$ (0.46)

	First Quarter Ended March 31, 2008	Second Quarter Ended June 30, 2008	Third Quarter Ended September 30, 2008	Fourth Quarter Ended December 31, 2008
		(Unaudited)		
Revenues	$ 56,383	$ 60,653	$ 65,584	$ 55,837
Net loss	(11,847)	(18,689)	(19,084)	(29,509)
Net loss per share, basic and diluted:	$ (0.15)	$ (0.24)	$ (0.24)	$ (0.37)

Samsung Bioepis Exhibit 1012 - Page 5447
Biocon Exhibit 1012 - Page 5447

Corporate information

Common stock and related matters

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market.

2008	HIGH	LOW
First Quarter	$ 25.25	$ 15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62
2009	**HIGH**	**LOW**
First Quarter	$ 20.08	$ 11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02

As of April 14, 2010, there were 459 shareholders of record of our Common Stock and 39 shareholders of record of our Class A Stock. The closing bid price for the Common Stock on that date was $26.39.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

Corporate office

777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
(914) 345-7400

Annual meeting

The 2010 Annual Meeting of Shareholders will be held on Friday, June 11, 2010 at 10:30 a.m. at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, NY 10591.

Shareholders' inquiries

Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent, American Stock Transfer & Trust Co., 59 Maiden Lane, Plaza Level, New York, NY 10038, (800) 937-5449. General information regarding the Company, recent press releases, and SEC filings are available on our web site at www regeneron.com, or can be obtained by contacting our Investor Relations Department at (914) 345-7741.

Transfer agent and registrar

American Stock Transfer & Trust Co.
59 Maiden Lane
Plaza Level
New York, NY 10038

Independent registered public accounting firm

PricewaterhouseCoopers LLP

REGENERON® and the following are registered trademarks of Regeneron Pharmaceuticals, Inc.: ARCALYST®, VelocImmune®, and VelociGene®. Lucentis® is a registered trademark of Genentech, Inc.

Forward-looking statements and risk factors

This Annual Report discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

Corporate directory

Directors

P. Roy Vagelos, M.D.
Chairman of the Board
Retired Chairman of the Board
and Chief Executive Officer,
Merck & Co., Inc.

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Charles A. Baker
Retired Chairman of the Board,
President and Chief Executive Officer,
The Liposome Company, Inc.

Michael S. Brown, M.D.
Regental Professor and Director,
Jonsson Center for Molecular Genetics
The University of Texas
Southwestern Medical Center at Dallas

Alfred G. Gilman, M.D., Ph.D.
Chief Scientific Officer,
Cancer Prevention and
Research Institute of Texas and
Regental Professor of Pharmacology
Emeritus
The University of Texas
Southwestern Medical Center at Dallas

Joseph L. Goldstein, M.D.
Regental Professor and Chairman,
Department of Molecular Genetics
The University of Texas
Southwestern Medical Center at Dallas

Arthur F. Ryan
Retired Chairman of the Board
and Chief Executive Officer,
Prudential Financial, Inc.

Eric M. Shooter, Ph.D.
Professor Emeritus,
Department of Neurobiology
Stanford University School of Medicine

George L. Sing
Chief Executive Officer, Stemnion, Inc. and
Managing Director, Lancet Capital

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President,
Chief Scientific Officer, and President,
Regeneron Research Laboratories

Senior management team

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President,
Chief Scientific Officer, and President,
Regeneron Research Laboratories

Murray A. Goldberg
Senior Vice President,
Finance and Administration,
Chief Financial Officer, Treasurer,
and Assistant Secretary

Stuart A. Kolinski
Senior Vice President,
General Counsel, and Secretary

Peter Powchik, M.D.
Senior Vice President,
Clinical Development

Neil Stahl, Ph.D.
Senior Vice President,
Research and Development Sciences

Robert J. Terifay
Senior Vice President,
Commercial

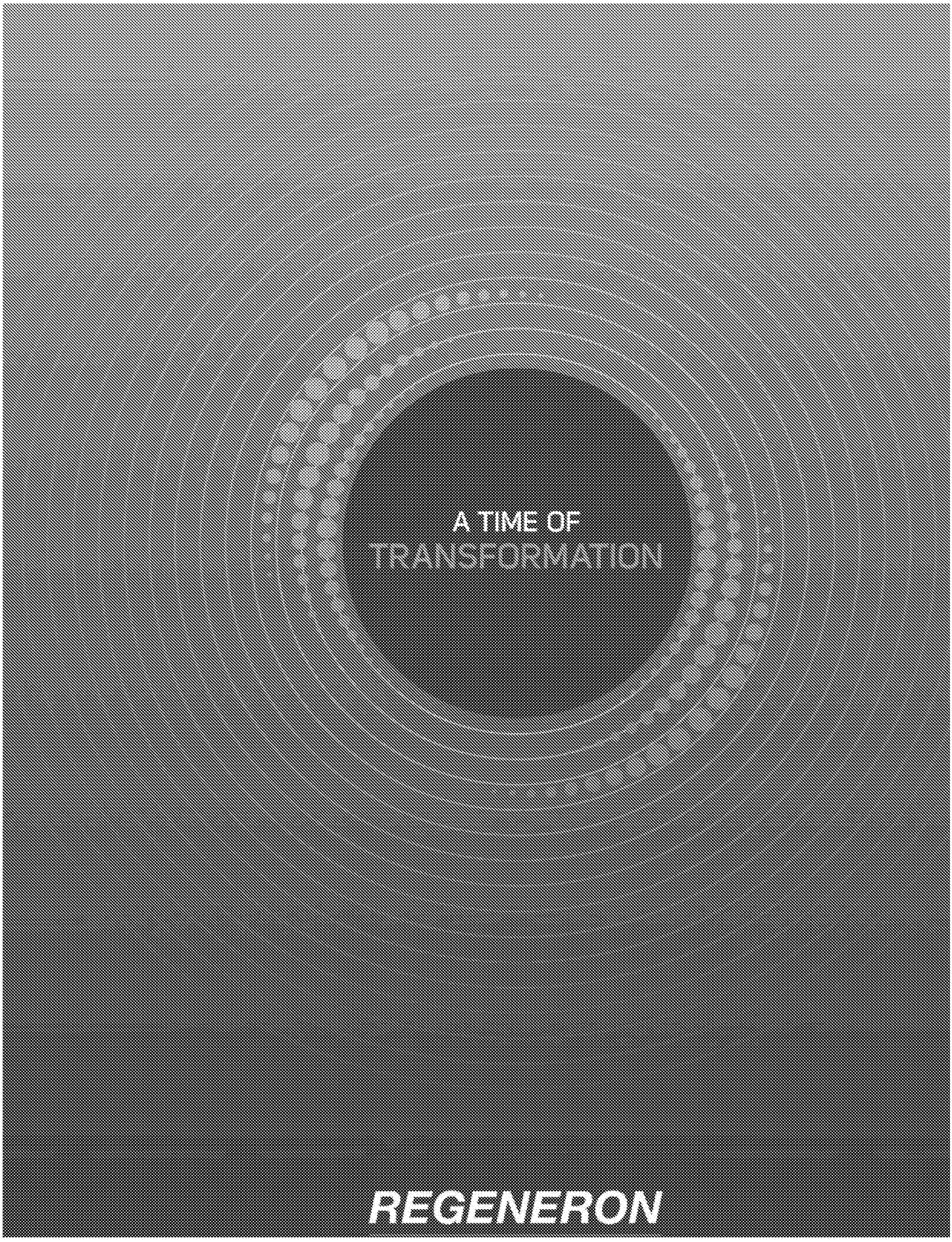
Daniel P. Van Plew
Senior Vice President
and General Manager,
Industrial Operations and Product Supply

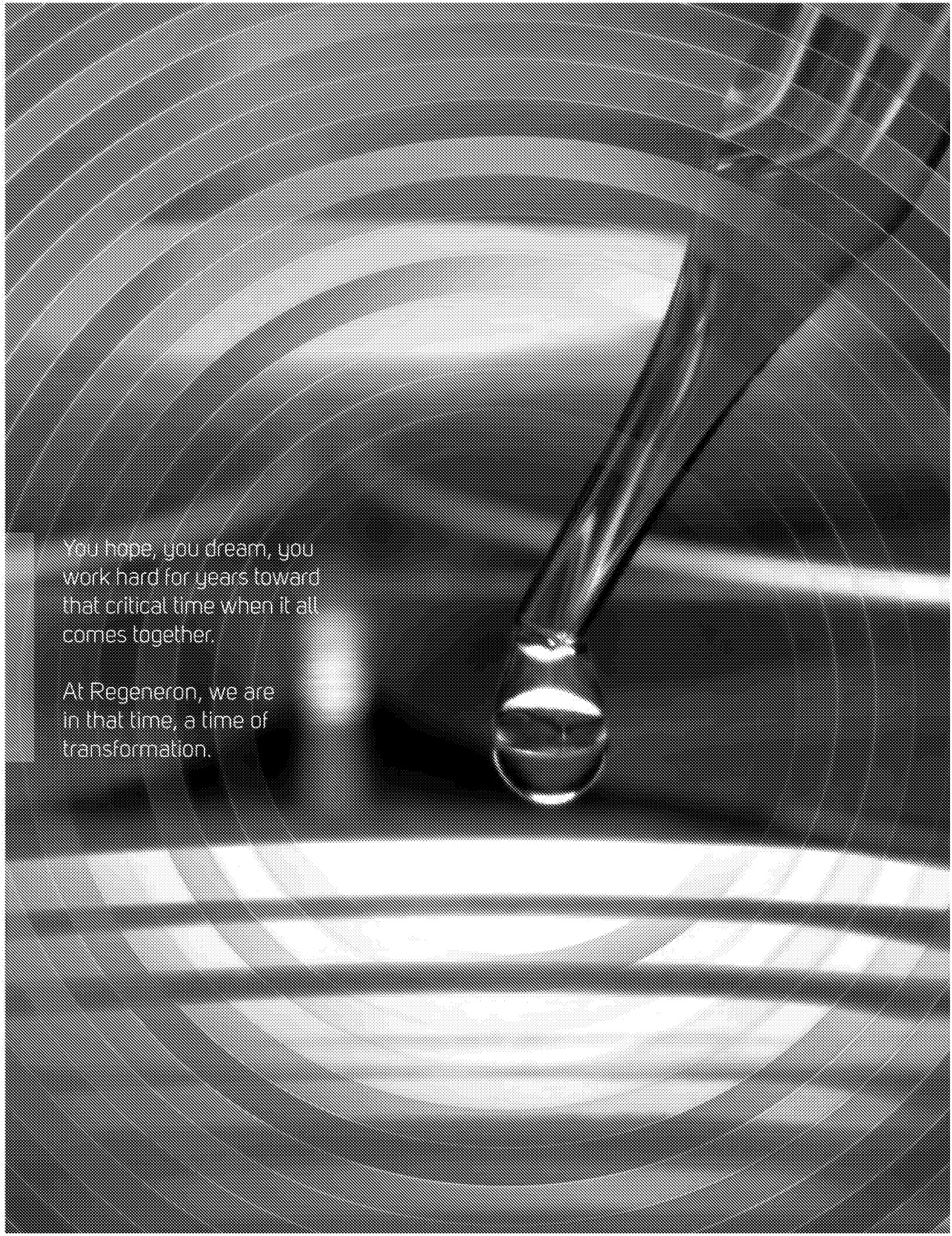
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Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591
www.regeneron.com

REGENERON


A TIME OF
TRANSFORMATION
REGENERON


You hope, you dream, you work hard for years toward that critical time when it all comes together.
At Regeneron, we are in that time, a time of transformation.

We have reached an important threshold in the transformation of our company. Positive clinical results in multiple Phase 3 programs and a focused, tenacious team



now 1,500 strong are bringing us closer to our goal of becoming a multi-product, fully integrated pharmaceutical company by delivering important medicines to patients with serious illnesses.

2010 Annual Report Shareholder Letter

WE ARE TRANSFORMING INTO A COMMERCIAL ENTERPRISE

Dear Shareholders,

The last 12 months have been transformative and unprecedented for Regeneron.

We reported positive Phase 3 clinical results from two trials in wet age-related macular degeneration (wet AMD), the most common cause of blindness in the elderly; from three trials in gout; and from the first of two trials in another serious eye disease, central retinal vein occlusion (CRVO).

Based on these data, we submitted our application to the U.S. Food and Drug Administration (FDA) for regulatory approval of VEGF Trap-Eye in the wet AMD indication and announced our intention to submit in mid-2011 an application for FDA approval of ARCALYST® (rilonacept) for the prevention of drug treatment-induced gout flares.

We are very pleased that in April 2011 the FDA accepted our VEGF Trap-Eye filing for review and granted it Priority Review status, a designation given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. With Priority Review, the target date for an FDA decision on our application has been set for August 20. Accordingly, if VEGF Trap-Eye is approved, we anticipate a U.S. product launch in wet AMD in the second half of 2011.

Before this annual report reaches shareholders, we expect to have released results of the second Phase 3 study we have been conducting with VEGF Trap-Eye in CRVO, and we intend to seek FDA approval for CRVO if the second Phase 3 study in this indication confirms the results of the first trial. Also imminent are results from our Phase 3 trial of aflibercept (VEGF Trap) in second-line colorectal cancer.



Pictured From Left to Right:

P. Roy Vagelos, M.D.
Chairman of the Board

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

George D. Yancopoulos, M.D., Ph.D.
Executive Vice President, Chief Scientific Officer
and President, Regeneron Research Laboratories

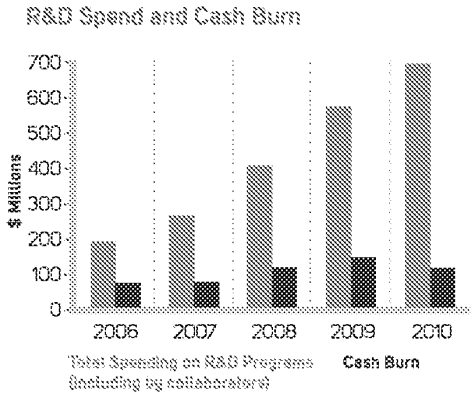
We announced in March 2011 that in the Phase 3 trial of aflibercept in second-line non-small-cell lung cancer, adding aflibercept to the chemotherapeutic agent docetaxel did not improve overall survival compared to docetaxel and placebo. Also, in February 2010, we announced that while ARCALYST® (rilonacept) was effective in preventing drug-induced gout flares in the first of our two Phase 3 trials in that indication, in another Phase 3 study it was not more effective than non-steroidal anti-inflammatory agents (NSAIDS) in treating acute gout flares once flares had started.

In the pharmaceutical industry, the journey to bring even one drug to market is long and arduous, so we are delighted to be close to the point of potentially commercializing two drugs for serious medical conditions — wet AMD and gout. Yet this is not the full story of Regeneron today. If biotechnology companies are fortunate enough to bring a drug to market after years of investment and uncertainty, then most face the tough challenge of building a pipeline that can sustain their growth. Regeneron already has that pipeline in place, with 11 compounds in various stages of clinical development. We also have the technology platforms, the personnel, and the financial resources, through our collaboration with sanofi-aventis, to advance and replenish our pipeline of fully human monoclonal antibodies.

In fact, we aim to introduce approximately 30 to 40 additional antibodies into clinical development by the end of 2017. One of the most promising programs in the pipeline today is REGN727, an antibody to a novel protein called PCSK9 that is believed to play a role in regulating production of LDL (bad) cholesterol. REGN727 is exciting because potentially it may provide an alternative for people who are unable to lower their cholesterol to recommended levels even by taking statin medications. The REGN727 program is described in further detail on page 7 of this report.

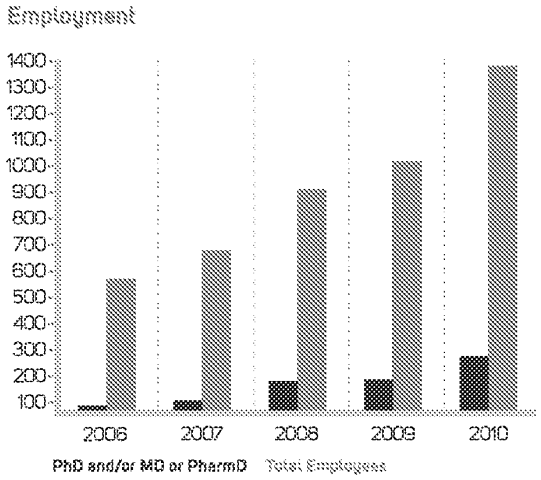
Since we entered into our antibody collaboration with sanofi-aventis in 2007, our research and clinical development program has grown to become one of the 10 largest in the biotech industry. We ourselves invested nearly $500 million on R&D in 2010. Total R&D spending on our programs, including spending by sanofi-aventis and Bayer HealthCare, our collaborator in the VEGF Trap-Eye program, climbed to almost $700 million last year.

Although our 2010 R&D spending was substantial, our use of cash — our "cash burn" in the language of the biotech industry — was only $125 million. The most important reason for this was the funding we received from our collaborators, sanofi-aventis and Bayer HealthCare. Additionally, ARCALYST® generated $20 million in product sales for its approved indication, the rare genetic disease called CAPS. Two other significant 2010 events enhanced our financial resources: we received an up-front $165 million payment from Astellas Pharma Inc. to extend its license to our VelocImmune® antibody generation technology; and we also took



advantage of favorable market conditions in October 2010 to raise $175 million through a public offering of our common stock, the first time we have gone to the public markets for capital since 2006. We ended 2010 with $627 million in cash and marketable securities.

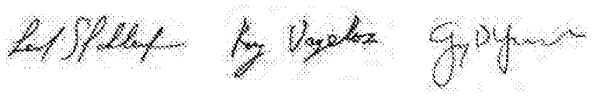
The year 2010 was also memorable in terms of organizational growth, as we increased staff by 36% to a total of about 1,400 employees. Most of the increase was in R&D to support the antibody collaboration. In the first quarter of 2011, we added over 80 more jobs and moved into a third new building at our Tarrytown campus. We currently count about 260 Ph.D.s and 50 M.D.s among our staff. The Industrial Operations and Product Supply (IOPS) department in Rensselaer is also growing. The group almost doubled production capacity in 2010 to 54,000 liters, while producing 60 lots of drug material for 11 different clinical programs. Our production facility and know-how are major — and often unrecognized — assets for Regeneron.



We have ambitious hiring targets for 2011, in large part to prepare for the potential commercialization of VEGF Trap-Eye for wet AMD and ARCALYST® for the gout flare prevention indication. We own exclusive U.S. rights to VEGF Trap-Eye and worldwide rights to ARCALYST®. We are also entitled to half of the profits from commercialization of VEGF Trap-Eye outside of the United States through our collaboration with Bayer HealthCare.

A sad event amidst the successes of the last year was the sudden death in November 2010 of our dear friend and colleague, Stuart A. Kolinski, Senior Vice President and General Counsel. Stuart, 45 years old, died the day after we reported the positive results in our two trials in wet AMD. Stuart made innumerable contributions to Regeneron during his 10 years with the company. He will be missed by all those who knew his drive, intellect, warmth, and humility.

As much as the past 12 months were a time of transformation, they were also a period of transition to new challenges: submitting a supplemental application for FDA review of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy and, potentially, for VEGF Trap-Eye in the CRVO indication; building a sales, marketing, and product distribution organization in the United States; preparing for potential product launches; and advancing our earlier-stage antibody candidates. We look forward to reporting back to you a year from now on our accomplishments in these endeavors. As always, we thank you, our shareholders, for your confidence and support.



2010 and 2011 Year-to-Date Highlights

February
We announced positive six-month data from the Phase 2 study (called DA VINCI) of VEGF Trap-Eye in patients with clinically significant diabetic macular edema (DME).

May
We reported positive proof-of-concept interim data from a Phase 1 study of the PCSK9 antibody (REGN727) for LDL (bad) cholesterol reduction and from a Phase 2 study of the nerve growth factor (NGF) antibody (REGN475) for pain.

June
We announced positive results for ARCALYST® in the first of two Phase 3 studies for the prevention of gout flares in patients initiating allopurinol therapy and unsuccessful results for ARCALYST® in treating acute gout flares once flares had started.

July
We held our first Investor Day in New York City. Nearly 200 people attended the event live or virtually on the Internet.

Astellas Pharma and Regeneron extended through 2023 Astellas' non-exclusive license to utilize the Regeneron Velocimmune® technology in its internal research programs to discover fully human monoclonal antibodies. Astellas paid the Company $165 million upfront and agreed to pay another $130 million in 2018.

October
We raised $175 million in a common stock offering, our first public financing since 2006.

November
We reported that VEGF Trap-Eye met the primary endpoint of non-inferiority to Lucentis® (ranibizumab), the market-leading anti-VEGF therapy, in the one-year analysis of two Phase 3 studies in wet age-related macular degeneration (wet AMD).

December
The U.S. FDA placed REGN475 on clinical hold following a case of avascular necrosis of a joint with another company's anti-NGF antibody.

We reported positive results for VEGF Trap-Eye in the first of two Phase 3 studies in central retinal vein occlusion and positive one-year results from the Phase 2 study in DME.

2011 Year-to-Date

February
We announced positive results for ARCALYST® in the second Phase 3 trial for the prevention of gout flares in patients initiating uric acid-lowering therapy.

We announced that three more antibodies have entered clinical development.

We submitted a Biologics License Application to the FDA for VEGF Trap-Eye for the treatment of wet AMD.

March
We announced that in the Phase 3 study of aflibercept (VEGF Trap) in second-line non-small-cell lung cancer, a regimen of aflibercept and chemotherapy did not show a survival benefit compared with chemotherapy alone.

April (up to press time)
We announced the start of a Phase 3 clinical program for VEGF Trap-Eye in DME.

We announced that the FDA has accepted for review our filing for VEGF Trap-Eye for the treatment of wet AMD, has granted the application Priority Review, and has set August 20, 2011 as the target date for an FDA decision.

Directors

P. Roy Vagelos, M.D.
Chairman of the Board; Retired Chairman of the Board and Chief Executive Officer, Merck & Co., Inc.

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President and Chief Executive Officer

Charles A. Baker
Retired Chairman of the Board, President and Chief Executive Officer, The Liposome Company, Inc.

Michael S. Brown, M.D.
Regental Professor and Director, Jonsson Center for Molecular Genetics, The University of Texas Southwestern Medical Center at Dallas

Alfred G. Gilman, M.D., Ph.D.
Chief Scientific Officer, Cancer Prevention and Research Institute of Texas and Regental Professor of Pharmacology Emeritus, The University of Texas Southwestern Medical Center at Dallas

Joseph L. Goldstein, M.D.
Regental Professor and Chairman, Department of Molecular Genetics, The University of Texas Southwestern Medical Center at Dallas

Christine A. Poon
Dean, The Max M. Fisher College of Business at The Ohio State University; Retired Vice Chairman and Worldwide Chairman of Pharmaceuticals, Johnson & Johnson

Arthur F. Ryan
Retired Chairman of the Board and Chief Executive Officer, Prudential Financial, Inc.

Eric M. Shooter, Ph.D.
Professor Emeritus, Department of Neurobiology, Stanford University School of Medicine

George L. Sing
Chief Executive Officer, Stemnion, Inc., and Managing Director, Lancet Capital

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Murray A. Goldberg
Senior Vice President, Finance and Administration, Chief Financial Officer, Treasurer and Assistant Secretary

Peter Powchik, M.D.
Senior Vice President, Clinical Development

Neil Stahl, Ph.D.
Senior Vice President, Research and Developmental Sciences

Robert J. Terifay
Senior Vice President, Commercial

Daniel Van Plew
Senior Vice President and General Manager, Industrial Operations and Product Supply

Corporate Information

Common Stock and Related Matters
Our Common Stock is traded on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market.

2009	HIGH	LOW
First Quarter	$20.08	$11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02

2010	HIGH	LOW
First Quarter	$30.51	$23.22
Second Quarter	30.38	22.32
Third Quarter	27.53	20.45
Fourth Quarter	33.94	24.29

As of April 13, 2011, there were 428 shareholders of record of our Common Stock and 37 shareholders of record of our Class A Stock. The closing sales price for the Common Stock on that date was $44.74.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

Corporate Office
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707
(914) 345-7400

SEC Form 10-K
A copy of our 2010 annual report on Form 10-K filed with the Securities and Exchange Commission (which accompanies and forms part of this 2010 Annual Report to Shareholders) is available without charge from the Regeneron Investor Relations Department.

Annual Meeting
The Annual Meeting will be held on Friday, June 10, 2011 at 10:30 a.m. at the Westchester Marriott Hotel, 670 White Plains Road, Tarrytown, NY 10591.

Shareholders' Inquiries
Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent, American Stock Transfer & Trust Co., 59 Maiden Lane, Plaza Level, New York, NY 10038, (800) 937-5449. General information regarding the Company, recent press releases and SEC filings are available on our web site at www.regeneron.com, or can be obtained by contacting our Investor Relations Department at (914) 345-7741.

Transfer Agent and Registrar
American Stock Transfer & Trust Co.
59 Maiden Lane
Plaza Level
New York, NY 10038

Independent Registered Public Accounting Firm
PricewaterhouseCoopers LLP

This Annual Report contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing and possible success and therapeutic applications of our product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the Sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third-party intellectual property. A more complete description of these and other material risks can be found in our filings with the Securities and Exchange Commission, including our Form 10-K for the year ended December 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

REGENERON

REGENERON® and the eye/leaf are registered trademarks of Regeneron Pharmaceuticals, Inc.
ARCALYST®, VelocImmune®, and VelociGene® IGHS-IP® are registered trademarks of Regeneron, Inc.

FSC Mixed Sources

DEVELOPING A DEEP AND BALANCED PIPELINE

Marketed

ARCALYST® (rilonacept)
Cryopyrin-Associated Periodic Syndromes (CAPS)

BLA

VEGF Trap-Eye
Wet age-related macular degeneration

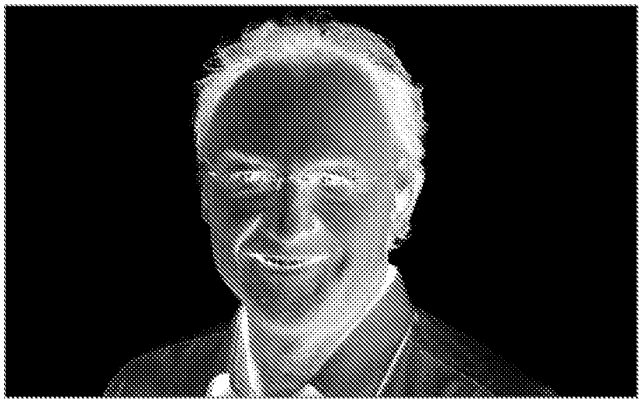
Phase 3

ARCALYST® (rilonacept)
Gout flare prevention in patients initiating uric acid-lowering therapy

VEGF Trap-Eye
Central retinal vein occlusion
Diabetic macular edema

Aflibercept (VEGF Trap)
2nd-line metastatic colorectal cancer
1st-line metastatic prostate cancer

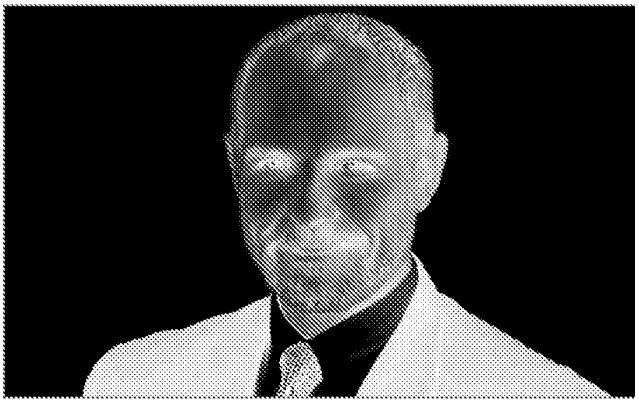
BECOMING A FULLY INTEGRATED PHARMACEUTICAL COMPANY



Neil Stahl, Ph.D.

Senior Vice President, Research and Development Sciences

"Our product candidates target a mix of validated and novel targets. Having a balanced portfolio helps manage the risk inherent in drug development."



Peter Powchik, M.D.

Senior Vice President, Clinical Development

"We have the enviable ability to add several additional fully human antibodies to the clinical pipeline each year due to the productivity of our discovery and development platforms."

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Biocon Exhibit 1012 - Page 5460

Phase 2

Aflibercept (VEGF Trap)
1st-line metastatic colorectal cancer

REGN727 (PCSK9 Antibody)
LDL cholesterol reduction

REGN475 (NGF Antibody)*
Osteoarthritis of the knee
**On Clinical Hold*

REGN88 (IL-6R Antibody)
Rheumatoid arthritis
Ankylosing spondylitis

REGN668 (IL-4R Antibody
Eosinophilic asthma

Phase 1

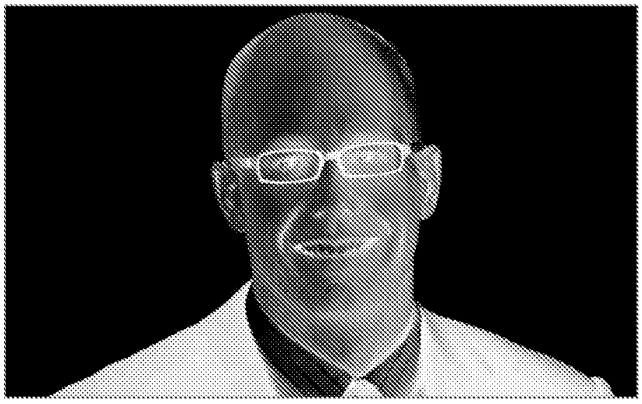
REGN421 (Dll4 Antibody)
Advanced malignancies

REGN668 (IL-4R Antibody)
Atopic dermatitis

REGN910 (ANG2 Antibody)
Cancer

REGN728
Undisclosed

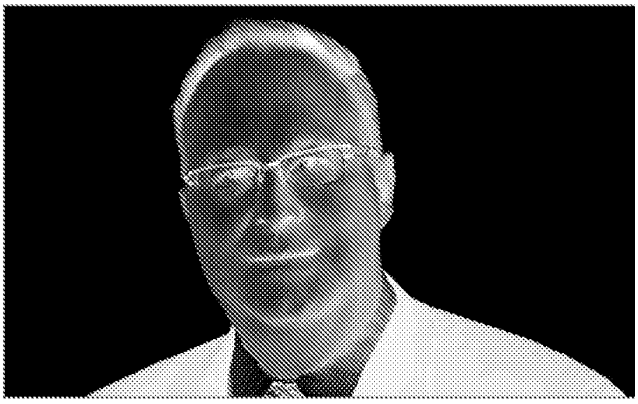
REGN846
Undisclosed



Daniel P. Van Plew

Senior Vice President and General Manager, Industrial Operations and Product Supply

"We've made major investments to build the know-how and infrastructure needed to supply our drug products."



Robert J. Terifay

Senior Vice President, Commercial

"This is a very exciting time at Regeneron as we complete regulatory filings and prepare for potential product launches in wet AMD and gout."

VEGF TRAP-EYE — A POTENTIAL NEW TREATMENT FOR SEVERAL SERIOUS EYE DISEASES

Uncontrolled buildup of fluid from leaky blood vessels in the macula, the light-sensitive part of the retina responsible for sharp, direct vision, can lead to irreparable damage to the macula and to vision loss. In recent years, medicines that block the activity of a blood vessel growth factor called VEGF (vascular endothelial growth factor) have not only stabilized vision in people losing their sight from these conditions, which include wet age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), and diabetic macular edema (DME); the medicines have actually restored vision in many patients by reversing the accumulation of fluid and swelling.

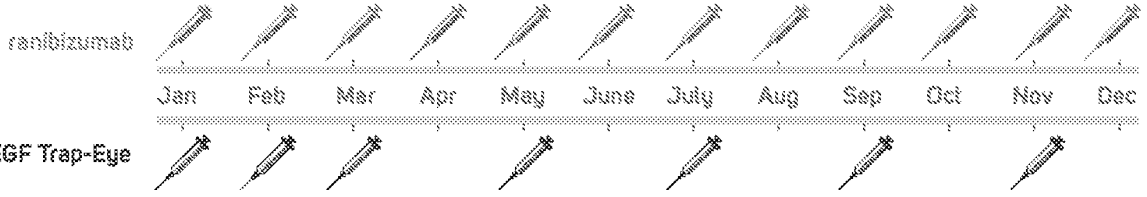
In February 2011, we submitted a regulatory application to the FDA to market our VEGF Trap-Eye drug candidate for wet AMD, the best known of these eye diseases and the leading cause of blindness in the elderly. Based on the Phase 3 clinical data, we and our collaborator, Bayer HealthCare, believe VEGF Trap-Eye is a novel anti-VEGF agent that, if approved by regulatory authorities, could be an effective therapy for the treatment of wet AMD when administered on an every two months dosing schedule. We are also encouraged by initial clinical results in CRVO and DME.

$3+ Billion | The global wet AMD market is growing > 20% annually

Phase 3 Trial Results in Wet AMD

In our two Phase 3 studies in wet AMD, 2-milligram (mg) doses of our drug candidate (VEGF Trap-Eye) given every two months achieved similar (the technical term is non-inferior) results in terms of maintaining vision to current standard-of-care anti-VEGF therapy: Lucentis® (ranibizumab) 0.5 mg dosed according to its label every four weeks. Average vision gains with the two therapies were also similar in these trials, as were the safety profiles of the two medicines.[1] Feedback from physicians we consulted suggests that treatment that requires half the dosing yet provides comparable predictable results would be a major advantage for patients. Today, many retinal specialists would like to treat patients less often than monthly but must examine them each month to determine if another treatment is needed. Monthly office visits, whether or not they result in treatments, are inconvenient for physicians and patients and burdensome for the caregiver who must bring the patient to the doctor's office because treated patients are not permitted to drive themselves home.

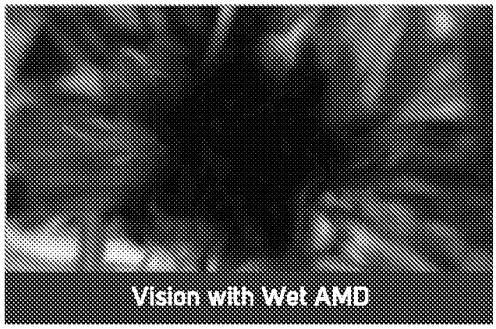
Phase 3 Trial Design
VEGF Trap-Eye vs. ranibizumab



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Wet AMD

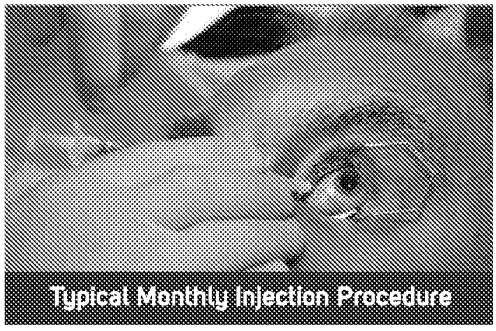
There are two forms of AMD: wet and dry. The wet form is responsible for about 80% to 90% of all AMD-related blindness, and it can develop at any time in people with dry AMD. Genetic predisposition, diet, and environmental risk factors contribute to the development of AMD, but changes due to aging may be the initial stimulus. More than 210,000 Americans are newly diagnosed with and treated for wet AMD each year. Prevalence of AMD in the United States is estimated at 1.8 million people (1.2 million of whom have wet AMD), and with the aging of the Baby Boom generation, is expected to increase to nearly 3 million by 2020.



Vision with Wet AMD

Central Retinal Vein Occlusion

CRVO is triggered by a blockage of the central retinal vein, typically from a blood clot or pressure from arteries in the retina. The blockage leads to a backup of blood and fluid that injures the retina. We and our collaborator Bayer HealthCare expect soon to report results from the second of two Phase 3 clinical trials of VEGF Trap-Eye in this indication. We reported positive results from the first study, called COPERNICUS, in December 2010.



Typical Monthly Injection Procedure

Diabetic Macular Edema

Patients with diabetes are at risk of developing fluid accumulation and swelling in the macula that is thought to be mediated by the production of VEGF and other blood vessel growth factors in response to a lack of oxygen. Among Americans who have had diabetes for 10 years, the incidence of DME is estimated at 20% of patients with type 1 diabetes and 25% of patients with type 2 diabetes who use insulin. We and Bayer HealthCare initiated the first of two planned Phase 3 studies in DME in April 2011 following a positive Phase 2 trial reported in February 2010 (six-month data) and December 2010 (12-month data).

[1] The incidence of eye treatment-related side effects was balanced across all treatment groups in both studies. The most frequent events were associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse eventswere conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters.

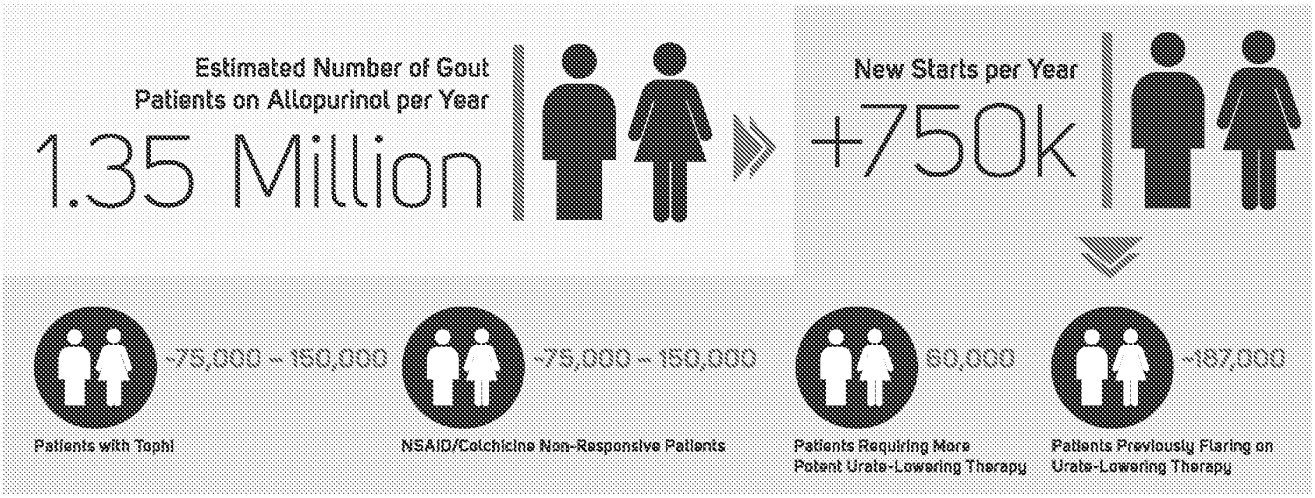
ARCALYST® (RILONACEPT) FOR PREVENTION OF DRUG-INDUCED GOUT FLARES

We Plan to File for Regulatory Review in Mid-2011

In our three Phase 3 studies, including two reported in the first quarter of 2011, all patients received a drug called allopurinol to reduce deposits of uric acid in joints, the standard approach to treating gout. The trials compared patients who were treated with allopurinol plus either a low or high dose of ARCALYST® or a placebo medicine. At both low and high doses, ARCALYST® was effective relative to placebo in preventing the occurrence of gout flares — the joint pain that is the major symptom of gout. The decrease in the mean number of flares was 73% to 80% in one trial, depending on the dose, and 72% in the second trial at both doses. The third Phase 3 study provided additional safety information. ARCALYST® was generally well tolerated in these studies. Injection site reactions, usually considered mild, were the most common side effect.

What Causes Gout?

Gout is a painful and often incapacitating form of arthritis that affects about three million Americans. Gout occurs when high blood levels of uric acid, a bodily waste product normally excreted by the kidneys, lead to the formation of crystals, typically in the toe and other joints. While allopurinol and newer uric acid-lowering medicines are often effective in reducing uric acid concentrations, many patients experience more rather than fewer flares during the first months of treatment as these medicines break down or increase the excretion of uric acid crystals from the joints into blood vessels.



Where ARCALYST® Fits in

ARCALYST® was designed to block the anti-inflammatory protein interleukin-1 (IL-1). IL-1 overproduction by infection-fighting cells in response to high concentrations of uric acid is believed to trigger acute gout flares, which generally persist for seven to 10 days. Non-steroidal anti-inflammatory agents (NSAIDs) and the drug colchicine are sometimes prescribed to manage gout flares for patients on uric acid-lowering therapy, but safety concerns and side effects limit their use. If ARCALYST® is approved by regulatory authorities, target populations will include people initiating uric acid-lowering therapy who are intolerant or unresponsive to NSAIDS or colchicine or have more severe gout, often involving protruding uric acid crystal deposits called tophi.