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 13, 2012 (February 13, 2012)

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) 847-7000
(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:

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

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

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

o 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 13, 2012, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and year ended December 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 7.01 Regulation FD Disclosure.

On February 13, 2012, Regeneron Pharmaceuticals Inc. (Company) provided the U.S. Food and Drug Administration (FDA) with information relating to adverse events reported to the Company for EYLEA® (aflibercept) Injection since the drug became commercially available in November, 2011. Among other things, the Company reported that since launch approximately 30,000 injections have been administered in the United States, and the Company has received reports of sterile intraocular inflammation following the administration of EYLEA at a rate of approximately 0.05% per injection. This rate was driven primarily by a cluster of events occurring at a single practice with the overall rate, excluding this practice, being approximately 0.01% per injection. The incidence of adverse events of intraocular inflammation reported thus far during commercial use of EYLEA is within the reported incidence in the literature with the intravitreal injection of anti-VEGF agents and other drugs as well as the rate observed during the clinical development program, even accounting for the possibility of underreporting. In addition, the lack of association of these adverse events with a single lot of drug product further led the Company to conclude that factors other than the drug are likely to be responsible for the occurrence of these events. The full letter to the FDA is furnished with this Current Report as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated February 13, 2012.

99.2 Letter to the FDA dated February 13, 2012.

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 13, 2012

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 dated February 13, 2012.
99.2	Letter to the FDA dated February 13, 2012.

REGENERON

For Immediate Release

Press Release

Regeneron Reports Fourth Quarter and Full Year 2011 Financial and Operating Results

- *EYLEA® (aflibercept) Injection Launched in U.S.; Over 30,000 Vials Shipped to Physicians Since Launch*
- *Full Year 2012 EYLEA U.S. Sales Forecast Increased from $140 – $160 million to $250 – $300 million*
- *Consistent with Pre-announced Sales, EYLEA Net Product Sales were $24.8 million in Fourth Quarter 2011*
- *Two Supplemental Biologics License Applications Submitted in Fourth Quarter 2011*

Tarrytown, New York (February 13, 2012) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced financial and operating results for the fourth quarter and full year 2011 and provided an update on development programs.

The Company reported total revenues of $123.0 million for the fourth quarter and $445.8 million for the year ended December 31, 2011. This includes EYLEA net product sales of $24.8 million for the fourth quarter of 2011. The Company reported a non-GAAP net loss of $34.0 million, or $0.37 per share (basic and diluted), for the fourth quarter and a non-GAAP net loss of $161.7 million, or $1.79 per share (basic and diluted), for the year ended December 31, 2011. Non-GAAP net loss excludes non-cash share-based compensation expense and non-cash interest expense related to the Company's convertible senior notes. The Company reported a GAAP net loss of $53.4 million, or $0.58 per share (basic and diluted), for the fourth quarter and a GAAP net loss of $221.8 million, or $2.45 per share (basic and diluted), for the year ended December 31, 2011.

Regeneron ended the year with approximately $811 million in cash and securities, following an offering of convertible senior notes in October 2011.

"2011 was a milestone year for Regeneron led by the approval and launch of EYLEA for the treatment of wet age-related macular degeneration in the United States," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "The EYLEA launch is off to a strong start, with net sales of $24.8 million from launch on November 21 through December 31, 2011. We look to continue to build on this success through 2012, and we now forecast 2012 U.S. EYLEA net product sales of $250 million to $300 million."

"In 2011, we also submitted supplemental Biologics License Applications (sBLA) to the FDA for EYLEA for the treatment of central retinal vein occlusion and for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapies," said George D. Yancopoulos, M.D., Ph.D., Executive Vice President, Chief Scientific Officer, and President, Regeneron Research Laboratories. "Regulatory actions on these sBLAs, as well as on a recently submitted BLA for ZALTRAP® for patients with previously treated metastatic colorectal cancer, are expected during 2012. Additionally, our collaborator Bayer HealthCare has submitted regulatory applications for EYLEA in Europe, Japan, and other countries, and our collaborator Sanofi has submitted a regulatory application for ZALTRAP in the EU. We are also pleased with progress in our pipeline, where ten antibodies are now in clinical development, including eight that are part of the Sanofi collaboration. Two antibodies - sarilumab for rheumatoid arthritis and REGN727 for hyperlipidemia - will be in Phase 3 testing in 2012."

Clinical Programs Update

EYLEA® (aflibercept) Injection – Ophthalmologic Diseases

EYLEA, known in the scientific literature as 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 EYLEA in the United States. Bayer HealthCare has rights to market EYLEA outside the United States, where the companies will share equally in profits from any future sales.

In November 2011, Regeneron announced that it received notification from the U.S. Food and Drug Administration (FDA) that the agency had approved EYLEA Injection for the treatment of patients with the neovascular form of age-related macular degeneration (wet AMD). The approval was granted under a Priority Review. During 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA in wet AMD in the European Union and Japan. Wet AMD is the leading cause of acquired blindness for people over the age of 65 in the United States and Europe.

In November 2011, Regeneron and Bayer HealthCare announced the initiation of a Phase 3 trial (SIGHT) evaluating the efficacy and safety of EYLEA in wet AMD in China. The SIGHT trial will include approximately 300 patients and will be the largest retinal trial conducted in China.

In December 2011, Regeneron and Bayer HealthCare also announced that in an integrated analysis of two parallel Phase 3 studies (VIEW 1 and VIEW 2) in patients with wet AMD, patients treated with EYLEA showed a sustained improvement in visual acuity at 96 weeks versus baseline with a safety profile similar to that reported in the first year of the study.

Regeneron has filed an sBLA for EYLEA in central retinal vein occlusion (CRVO) in the United States, and was granted a Prescription Drug User Free Act (PDUFA) date of September 23, 2012. Bayer HealthCare plans to submit a similar regulatory application outside the United States in 2012 or early 2013.

Earlier this year, Regeneron and Bayer HealthCare initiated two Phase 3 trials of EYLEA in a third indication, diabetic macular edema (DME). The VISTA-DME U.S. trial has completed enrollment and the VIVID-DME global trial is enrolling patients.

Regeneron and Bayer HealthCare also initiated a Phase 3 trial in Asia in collaboration with the Singapore Eye Research Institute in patients with choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia.

Regeneron plans on initiating a Phase 3 study in branch retinal vein occlusion (BRVO) in the first quarter of 2012.

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 Sanofi for the potential treatment of patients with solid tumors.

As previously reported in June 2011, in the Phase 3 study (called VELOUR) of ZALTRAP in previously treated metastatic colorectal cancer (mCRC) patients, the addition of ZALTRAP to the FOLFIRI chemotherapy regimen (folinic acid [leucovorin], 5-fluorouracil, and irinotecan) significantly improved both overall survival (HR=0.817; p=0.0032) and progression-free survival (HR=0.758; p=0.00007) compared to FOLFIRI plus placebo. A similar effect was seen with ZALTRAP therapy whether or not patients had received prior bevacizumab therapy.

In the VELOUR study, grade 3 or 4 adverse events (AEs) that occurred with a more than two percent greater incidence in the ZALTRAP arm than in the placebo arm included diarrhea, asthenia/fatigue, stomatitis/ulceration, infections, hypertension, GI/abdominal pains, neutropenia, neutropenic complications, and proteinuria. Deaths on study treatment due to AEs occurred in 2.4 percent of patients in the ZALTRAP arm and in 1.0 percent of patients in the placebo arm.

Based upon these positive results from the VELOUR study, regulatory applications for marketing approval of ZALTRAP were submitted to the FDA and European Medicines Agency.

As previously reported in December 2011, initial data from the Phase 2 AFFIRM study in the first-line mCRC setting showed that in patients who received ZALTRAP in combination with the modified FOLFOX6 regimen (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin), the Progression Free Survival (PFS) rate at one year was similar to that seen in the standard therapy arm for patients who received the modified FOLFOX6 regimen alone. The safety profile of ZALTRAP was similar to what was seen in prior trials.

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.

In the fourth quarter of 2011, Regeneron submitted an sBLA for ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering therapy and was granted a PDUFA date of July 30, 2012. Regeneron owns worldwide rights to ARCALYST.

Monoclonal Antibodies

Since 2007, Regeneron and Sanofi have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology.

The following ten antibody candidates are currently in clinical development, eight under the collaboration with Sanofi:

Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), is in the Phase 3 stage of a Phase 2/3 study (MOBILITY) in rheumatoid arthritis (RA).

In July 2011, Regeneron and Sanofi announced results from Phase 2b trials in RA with sarilumab. The Phase 2b MOBILITY trial in RA demonstrated that patients treated with sarilumab in combination with a standard RA treatment, methotrexate (MTX), achieved a significant and clinically meaningful improvement in signs and symptoms of moderate-to-severe RA compared to patients treated with MTX alone. The MOBILITY study is a 306-patient, dose-ranging, multi-national, randomized, multi-arm, double-blind, placebo-controlled study, that compared five different dose regimens of sarilumab in combination with MTX to placebo plus MTX. The most common adverse events (>5%) reported more frequently in active treatment arms included infections (non-serious), neutropenia, and liver function test abnormalities. The types and frequencies of adverse events were consistent with those previously reported with IL-6 inhibition. The incidence of serious adverse events among the five sarilumab treatment groups and placebo group were comparable. Sarilumab also demonstrated significant benefit compared to placebo in secondary endpoints, including ACR 50, ACR 70, and DAS 28 scores, additional measures of clinical activity used in RA trials.

REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, is in Phase 2 studies. During 2011, three Phase 2 studies with subcutaneous regimens of REGN727 were initiated: (1) a randomized, double-blind, multi-dose, placebo controlled, 75-patient trial in patients with heterozygous familial hypercholesterolemia (heFH), (2) a randomized, double-blind, multi-dose, placebo controlled, 90-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia, and (3) a randomized, double-blind, multi-dose, placebo controlled, 180-patient trial in combination with atorvastatin in patients with primary hypercholesterolemia and on stable doses of atorvastatin. The primary endpoint of each Phase 2 study is the change in LDL cholesterol from baseline compared to placebo over the study period.

In November 2011, Regeneron announced preliminary results from the Phase 2 heFH trial. In the primary efficacy analysis of the study, after 12 weeks of treatment, patients who received different dosing regimens of REGN727 achieved mean LDL cholesterol reductions from baseline ranging from approximately 30% to greater than 65%, depending on the dosing regimen of REGN727, compared to a mean reduction of 10% with placebo ($p<0.05$ for all dose groups). In this trial, REGN727 was generally well tolerated over 12 weeks. The most common adverse event was injection site reaction and there were no serious adverse events on active treatment. Additional data from the 8-week post-treatment safety monitoring period will be presented at a future medical congress upon final analysis.

In November 2011, Regeneron also announced preliminary results from the Phase 2 trial studying patients with primary hypercholesterolemia who were on stable doses of atorvastatin. In the primary endpoint of the study, after eight weeks of treatment, patients who received REGN727 plus atorvastatin 80 milligrams (mg) achieved a greater than 65% reduction in mean LDL cholesterol compared to a mean reduction of 17% for atorvastatin 80mg only ($p<0.001$). The study also included a third arm in which REGN727 was added to a stable low dose of atorvastatin, and the patients achieved a greater than 65% reduction in mean LDL cholesterol. In this trial, REGN727 was generally well tolerated over 16 weeks. There was one serious adverse event of dehydration in the REGN727 plus atorvastatin 80mg group that was deemed not treatment related. One patient in the REGN727 plus atorvastatin 80mg group with mildly elevated aspartate aminotransferase (AST) prior to randomization (>ULN and </= 3ULN) experienced an elevation of AST>3ULN and </=5ULN, and one patient discontinued therapy due to a hypersensitivity reaction (rash).

Initial data from the third Phase 2 trial, studying subcutaneous regimens of REGN727 in combination with atorvastatin in patients with primary hypercholesterolemia, will be available in the first half of 2012.

Regeneron and Sanofi are finalizing plans for initiating a Phase 3 program for REGN727.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, is in a Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma.

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

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

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in osteoarthritis of the knee. In December 2010, the FDA informed the Company that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. An FDA Arthritis Advisory Committee is scheduled to meet on March 12, 2012 to discuss possible safety issues related to anti-NGF compounds. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

REGN728, whose target remains undisclosed, is in a Phase 1 study.

REGN1033, whose target remains undisclosed, will enter Phase 1 studies in the first quarter of 2012.

REGN846, whose target remains undisclosed, is being evaluated in a Phase 2a study in patients with atopic dermatitis. In July 2011, Sanofi elected not to continue co-development of REGN846, and Regeneron now has sole global rights to REGN846. Under the terms of the companies' agreement, Sanofi remains obligated to fund REGN846 clinical costs through conclusion of a planned proof-of-concept trial and is entitled to receive a mid-single digit royalty on any future sales of REGN846.

REGN1154, whose target remains undisclosed, will enter Phase 1 studies in the first quarter of 2012. Sanofi did not opt in to development of REGN1154. Regeneron has sole global rights to REGN1154, and Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN 1154.

Fourth Quarter and Full Year 2011 Financial Results

Total Revenues: Total revenues were $123.0 million for the fourth quarter and $445.8 million for the full year 2011, compared to $133.7 million for the fourth quarter and $459.1 million for the full year 2010. Total revenues include total collaboration revenues of $86.4 million for the fourth quarter and $369.7 million for the full year 2011, compared to $117.0 million for the fourth quarter and $386.7 million for the full year 2010.

Product Revenues: Net product sales were $29.8 million for the fourth quarter and $44.7 million for the full year 2011, compared to net product sales of $5.3 million for the fourth quarter and $25.3 million for the full year 2010. The increase in net product sales is due to the approval and launch of EYLEA in November 2011. EYLEA net product sales for the fourth quarter and full year 2011 were $24.8 million. ARCALYST net product sales for the fourth quarter 2011 were $5.0 million, compared to $5.3 million for the fourth quarter 2010. ARCALYST net product sales for the full year 2011 were $19.9 million, compared to $25.3 million 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.

Research and Development (R&D) Expenses: In 2011, GAAP R&D expenses were $129.0 million for the fourth quarter and $529.5 million for the full year, compared to $125.2 million for the fourth quarter and $489.2 million for the full year 2010. The higher R&D expenses in 2011 were primarily related to higher R&D headcount, research and preclinical development activities, principally in connection with the Sanofi antibody collaboration, and higher non-cash share-based compensation expense. In 2011, R&D related non-cash share-based compensation expense was $9.2 million for the fourth quarter and $32.8 million for the full year, compared to $7.0 million for the fourth quarter and $22.3 million for the full year 2010.

Selling, General, and Administrative (SG&A) Expenses: In 2011, GAAP SG&A expenses were $36.3 million for the fourth quarter and $117.3 million for the full year, compared to $20.6 million for the fourth quarter and $65.2 million for the full year 2010. The higher SG&A expenses in 2011 were primarily related to higher selling expenses in connection with commercialization of EYLEA, higher SG&A headcount, higher recruiting and non-cash share-based compensation expense, and higher legal expenses in connection with our patent litigation with Genentech. In 2011, SG&A related non-cash share-based compensation expense was $6.3 million for the fourth quarter and $23.3 million for the full year, compared to $6.6 million for the fourth quarter and $17.6 million for the full year 2010.

Cost of Goods Sold (COGS): In 2011, COGS was $3.0 million for the fourth quarter and $4.2 million for the full year 2011, compared to $0.6 million for the fourth quarter and $2.1 million for the full year 2010. The increase in COGS in 2011 was primarily due to the launch of EYLEA in the fourth quarter of 2011.

Interest Expense: In 2011, GAAP interest expense was $9.5 million for the fourth quarter and $21.3 million for the full year, compared to $2.5 million for the fourth quarter and $9.1 million for the full year 2010. In the fourth quarter and full year 2011, interest expense included $1.5 million of cash interest expense and $3.9 million of non-cash interest expense related to the Company’s convertible senior notes, which were issued in October 2011.

Non-GAAP and GAAP Net Loss: The Company reported a non-GAAP net loss of $34.0 million, or $0.37 per share (basic and diluted), for the fourth quarter 2011, compared to a non-GAAP net loss of $1.1 million, or $0.01 per share (basic and diluted), for the fourth quarter 2010. The Company had a non-GAAP net loss of $161.7 million, or $1.79 per share (basic and diluted), for the year ended 2011, compared to a non-GAAP net loss of $64.6 million, or $0.78 per share (basic and diluted), for the year ended 2010. Non-GAAP net loss excludes non-cash share-based compensation expense and non-cash interest expense related to the convertible senior notes.

The Company reported a GAAP net loss of $53.4 million, or $0.58 per share (basic and diluted), for the fourth quarter 2011, compared to a GAAP net loss of $14.6 million, or $0.17 per share (basic and diluted), for the fourth quarter 2010. The Company had a GAAP net loss of $221.8 million, or $2.45 per share (basic and diluted), for the full year 2011, compared to a GAAP net loss of $104.5 million, or $1.26 per share (basic and diluted), for the full year 2010.

Cash Position: At December 31, 2011, cash and marketable securities totaled $810.6 million (including $7.7 million of restricted cash and marketable securities) compared to $626.9 million (including $7.5 million of restricted cash and marketable securities) at December 31, 2010. In October 2011, the Company completed a private offering of $400 million aggregate principal amount of 1.875% convertible senior notes. The net proceeds of the offering were $391.1 million after deducting the initial purchaser's discount and offering expenses. In connection with the offering of the notes, the Company entered into convertible note hedge and warrant transactions with multiple counterparties. The net cost of the convertible note hedge transactions, after taking into account the proceeds received by the Company from the warrant transactions, was $23.7 million.

Use of Non-GAAP Financial Measures: The Company believes that the presentation of non-GAAP measures is useful to investors because it excludes (i) non-cash share-based compensation expense which fluctuates from period to period based on factors that are not within the Company's control such as the Company's stock price on the dates share-based grants are issued and (ii) non-cash interest expense related to the Company's convertible senior notes since this is not deemed useful in evaluating the Company's operating performance. Furthermore, management uses these non-GAAP measures for planning, budgeting, forecasting, in assessing historical performance, and in making financial and operational decisions, and also may provide forecasts to investors on this basis. However, there are limitations in the use of these non-GAAP financial measures as it excludes certain expenses that are recurring in nature. Furthermore, our non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. The non-GAAP financial measures should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of our GAAP to non-GAAP results is included on Table 3 within this press release.

Conference Call Information

Regeneron will host a conference call and simultaneous webcast to discuss its fourth quarter and full year 2011 financial and operating results on Monday, February 13, 2012, at 8:30 AM. To access this call, dial (888) 660-6127 (U.S) or (973) 890-8355 (International). A link to the webcast may be accessed from the 'Events and Presentations' page of Regeneron's website at www.regeneron.com. A replay of the conference call and webcast will be archived on the Company's website and will be available for 30 days.

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 in the United States, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA® (aflibercept) Injection, and has filed regulatory applications with the U.S. Food and Drug Administration (FDA) for second indications for each of these products. A regulatory application has also been submitted to FDA for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Phase 3 studies are in progress with EYLEA® in a third indication, with ZALTRAP® in a second indication, and with product candidate Sarilumab. Earlier-stage clinical programs are underway with nine additional product candidates. Regeneron has active research and development programs in many disease areas, including ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information 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 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 EYLEA and ARCALYST and Regeneron's product candidates, potential new indications for marketed products, 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 and new indications for marketed products, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA and other product and drug candidates and possible new indications for marketed products, competing drugs that may be superior to EYLEA and Regeneron’s product and drug candidates and possible new indications for marketed products, uncertainty of market acceptance of EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products, unforeseen safety issues resulting from the administration of products and product candidates in patients, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance, 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, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise, unless required by law.

This news release and/or the financial results attached to this news release include amounts that are considered "non-GAAP financial measures" under SEC rules. As required, we have provided reconciliations of these measures.

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TABLE 1

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS (Unaudited)

(In thousands)

	December 31, 2011	December 31, 2010
ASSETS		
Cash, restricted cash, and marketable securities	$ 810,550	$ 626,939
Accounts receivable from Sanofi	74,781	79,603
Accounts receivable - trade, net	28,254	2,314
Property, plant, and equipment, net	367,955	347,450
Other assets	42,043	33,126
Total assets	$ 1,323,583	$ 1,089,432
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	$ 102,068	$ 61,008
Deferred revenue	300,250	340,579
Facility lease obligations	160,514	160,030
Convertible senior notes	275,019	
Stockholders' equity	485,732	527,815
Total liabilities and stockholders' equity	$ 1,323,583	$ 1,089,432

TABLE 2

REGENERON PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	For the three months ended December 31,		For the year ended December 31,	
	2011	**2010**	**2011**	**2010**
Revenues				
Sanofi collaboration revenue	$ 77,032	$ 82,137	$ 326,609	$ 311,332
Other collaboration revenue	9,374	34,910	43,072	75,393
Net product sales	29,752	5,269	44,686	25,254
Technology licensing	5,892	10,038	24,858	40,150
Contract research and other	927	1,321	6,599	6,945
	122,977	133,675	445,824	459,074
Expenses				
Research and development	129,041	125,212	529,506	489,252
Selling, general, and administrative	36,349	20,641	117,261	65,201
Cost of goods sold	2,989	599	4,216	2,093
	168,379	146,452	650,983	556,546
Loss from operations	(45,402)	(12,777)	(205,159)	(97,472)
Other income (expense)				
Investment income	799	638	3,549	2,122
Interest expense	(9,455)	(2,458)	(21,282)	(9,118)
	(8,656)	(1,820)	(17,733)	(6,996)
Net loss before income tax benefit	(54,058)	(14,597)	(222,892)	(104,468)
Income tax benefit	(615)		(1,132)	
Net loss	$ (53,443)	$ (14,597)	$ (221,760)	$ (104,468)
Net loss per share, basic and diluted	$ (0.58)	$ (0.17)	$ (2.45)	$ (1.26)
Weighted average shares outstanding, basic and diluted	91,797	87,405	90,610	82,926

TABLE 3

REGENERON PHARMACEUTICALS, INC.

RECONCILIATION OF GAAP NET LOSS TO NON-GAAP NET LOSS (Unaudited)

(In thousands, except per share data)

	For the three months ended December 31,		For the year ended December 31,	
	2011	**2010**	**2011**	**2010**
GAAP net loss	$ (53,443)	$ (14,597)	$ (221,760)	$ (104,468)
Adjustments:				
R&D: Non-cash share-based compensation expense (1)	9,198	6,953	32,757	22,265
SG&A: Non-cash share-based compensation expense (1)	6,314	6,586	23,315	17,581
Interest expense: Non-cash interest related to convertible senior notes (2)	3,944		3,944	
Non-GAAP net loss	$ (33,987)	$ (1,058)	$ (161,744)	$ (64,622)
Non-GAAP net loss per share - basic	$ (0.37)	$ (0.01)	$ (1.79)	$ (0.78)
Non-GAAP net loss per share - diluted	$ (0.37)	$ (0.01)	$ (1.79)	$ (0.78)
Shares used in calculating:				
Non-GAAP net loss per share - basic	91,797	87,405	90,610	82,926
Non-GAAP net loss per share - diluted	91,797	87,405	90,610	82,926

(1) To exclude non-cash compensation expense related to employee stock option and restricted stock awards

(2) To exclude non-cash interest expense related to the amortization of the debt discount and debt issuance costs on our 1.875% convertible senior notes

REGENERON

REGENERON PHARMACEUTICALS, INC.
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591-6707

February 13, 2012

Dr. Renata Albrecht
Director, Division of Transplantation and Ophthalmology Products
Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: BLA 125387, Sequence No. 0055
EYLEA (aflibercept) Injection – Post Marketing Reports: Post-Injection Intraocular Inflammation

Dear Dr. Albrecht,

Reference is made to BLA 125387 for EYLEA® (aflibercept) Injection for the treatment of neovascular “wet” age-related macular degeneration (AMD).With this letter we would like to bring to your attention some reports of post-injection intraocular inflammation, reported during commercial use of EYLEA.

Post injection sterile intraocular inflammation is a known risk following intravitreal injections of anti-VEGFs and triamcinolone. Incidence rates reported in the literature can vary from 0.02 – 0.3% and have been reported to occur in clusters. In the largest case series reported to date, Moshfeghi et al described 12 cases out of 60,322 anti-VEGF injections that developed post injection inflammation (0.02% per injection).[1] Day et al conducted a retrospective, longitudinal case-control study using the Medicare 5% claim database. Based on an evaluation of 40,903 intravitreal injections of anti-VEGF agents, an endophthalmitis rate of 0.09% (37 cases) and a uveitis rate of 0.11% (45 cases) were reported.[2] Chong et al reported 44 cases of sterile inflammation after intravitreal injection of bevacizumab (0.27% of 16,166 injections). Seventeen inflammatory reactions were clustered around specific dates, which suggests a possible relation to drug preparation, though a specific cause remains unclear.[3] Roth et al described a cluster of 7 patients out of 104 who developed culture-negative endophthalmitis, following triamcinolone injection for macular edema. All 7 cases experienced painless, but severe inflammation within 2 days of intravitreal injection.[4] In Ness et al, a cluster of 10 cases of “toxic vitritis” developed after intravitreal injection of bevacizumab -- 6 patients were culture-negative and the remaining 4 were not cultured. The authors attributed these cases to a toxic reaction from the syringe brand used. No further cases occurred after changing to another brand of syringe.[5]

In the Phase 3 clinical development program for EYLEA in wet AMD a total number of 26,366 injections of EYLEA were administered through the end of the study at Week 96. There were 14 reports of events of clinically important intraocular inflammation (0.05% per injection). Of these, 5 cases were reported as endophthalmitis (0.02% per injection), of which 3 were identified as culture positive endophthalmitis. A total number of 9,805 injections of ranibizumab (Lucentis®, Genentech), the comparator agent, were administered through Week 96. Nine cases of clinically important intraocular inflammation were reported (0.09% per injection). Of these, 5 cases were reported as endophthalmitis (0.05% per injection), of which 2 were identified as culture positive endophthalmitis.

To date, approximately 30,000 injections of EYLEA have been administered in the United States since the drug became commercially available in November 2011. As of February 9, 2012, fourteen cases of adverse events consistent with sterile intraocular inflammation (an approximate rate of 0.05% per injection), following the use of EYLEA, have been reported to Regeneron Pharmaceuticals, Inc. In addition, we have received reports of one case of culture positive endophthalmitis, one case of corneal decompensation/toxic endotheliitis, and an additional patient with corneal decompensation with no evidence of inflammation in a patient with a history of Fuchs' Corneal Dystrophy.

Of note, one group practice of 6 physicians who have administered approximately 700 doses of EYLEA reported 11 of the 13 cases of sterile intraocular inflammation, with one physician in the group accounting for 9 of the 11 cases. This included an initial report of 7 cases with an additional 4 cases reported approximately 3 weeks later. Approximately half underwent vitreal tap and culture. None of these cases were culture positive. The inflammatory reaction MedDRA Preferred Term) reported in two of these cases was iritis, 8 reports included endophthalmitis, pseudoendophthalmitis, and/or vitritis; the 11th case was of 'redness and pain,' which received a vitreous tap. Multiple shipments of different lots of drug product were made to this practice, and the cases could not be traced to a single lot of drug product or a single delivery of commercial vials. Vials from the same lots have been widely used throughout the country. Review of drug manufacturing quality records did not reveal any product quality issues. We continue to work with this practice to try to define any potential cause for this cluster of cases.

Excluding this one practice, the rate of intraocular inflammation, reported to Regeneron, following the use of EYLEA was approximately 0.01% per injection (~1/10,000).

For all cases of sterile inflammation for which we have follow-up information (9 of 14) the patients are either improving or resolved. Additional -follow-up has been requested.

Receipt of these cases resulted in informal inquiries by Regeneron with a number of large practices, each with several retinal physicians who have cumulatively used EYLEA in approximately 3500 injections. The purpose of these inquiries was to proactively identify any additional cases of intraocular inflammation with the use of EYLEA. These inquiries identified one potential additional case of sterile inflammation for which we have requested, but not received information.

In summary, since the launch of EYLEA we have received reports of sterile intraocular inflammation following the administration of EYLEA at a rate of approximately 0.05%. This rate was driven primarily by a cluster of events occurring at a single practice with the overall rate, excluding this practice, being approximately 0.01%. The incidence of adverse events of intraocular inflammation reported thus far during commercial use of EYLEA is within the reported incidence in the literature with the intravitreal injection of anti-VEGF agents and other drugs as well as the rate observed during the clinical development program, even accounting for the possibility of underreporting. In addition, the lack of association of these adverse events with a single lot of drug product further leads us to conclude that factors other than the drug are likely to be responsible for the occurrence of these events. Post marketing reports will continue to be closely monitored for any reports consistent with intraocular inflammation.

The current Prescribing Information for EYLEA highlights the risk and recommends appropriate instructions for physicians and patients, regarding intraocular inflammation in its most serious form, endophthalmitis. This includes information to the prescriber within the Highlights, Warnings and Precautions, Administration, Adverse Reactions, and Patient Counseling Information sections.

Information related to the electronic content of the submission is provided in the cover letter attachment.

Sincerely,

William G. Roberts, M.D.
Vice President, Regulatory Development and Medical Safety

Cc: Dr. Wiley Chambers

References:

1. Moshfeghi A et al. Endophthalmitis after intravitreal anti-vascular endothelial growth factor antagonists: a six-year experience at a university referral center. *Retina* 2011;31:662-668.

2. Day S et al. Ocular Complications After Anti–Vascular Endothelial Growth Factor Therapy in Medicare Patients With Age-Related Macular Degeneration. *Am J Ophthalmol* 2011;152:266–272.

3. Chong DY et al. Characterization of sterile intraocular inflammatory responses after intravitreal bevacizumab injection. *Retina* 2010;30:1432-1440.

4. Roth DB et al. Noninfectious endophthalmitis associated with intravitreal triamcinolone injection. *Arch Ophthalmol* 2003;212:1279-1282.

5. Ness T et al. Toxic Vitreitis outbreak after intravitreal injection. *Retina* 2010;30:332-338.