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

# FORM 10-K

(Mark One)

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

**For the fiscal year ended December 31, 2013**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number 0-19034**

# REGENERON PHARMACEUTICALS, INC.

*(Exact name of registrant as specified in its charter)*

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

**(914) 847-7000**
*(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 a 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 a

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 a 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 a No _

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§232.405 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 |
|---|---|---|---|
| a | _ | _ | _ |

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $21,192,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 28, 2013, the last trading day of the registrant's most recently completed second fiscal quarter. For purposes of this calculation only, the registrant has assumed that all of its directors and executive officers, and no other persons, are its affiliates. This determination of affiliate status is not necessarily a determination for other purposes.

The number of shares outstanding of each of the registrant's classes of common stock as of February 6, 2014:

| Class of Common Stock | Number of Shares |
|---|---|
| Class A Stock, $.001 par value | 2,020,481 |
| Common Stock, $.001 par value | 97,907,887 |

**DOCUMENTS INCORPORATED BY REFERENCE:**

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2014 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K.
Exhibit index is located on pages 83 to 87 of this filing.

**REGENERON PHARMACEUTICALS, INC.**
**ANNUAL REPORT ON FORM 10-K**
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# 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 performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation EYLEA®, sarilumab, alirocumab, and dupilumab; ongoing regulatory obligations and oversight impacting our research and clinical programs and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures and income tax obligations, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property and pending or future litigation relating thereto. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part I, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.*

### General

Regeneron Pharmaceuticals, Inc. is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Our total revenues were $2,104.7 million in 2013, compared to $1,378.5 million in 2012 and $445.8 million in 2011. Our net income was $424.4 million, or $3.81 per diluted share, in 2013, compared to net income of $750.3 million, or $6.75 per diluted share, in 2012, and a net loss of $221.8 million, or $2.45 per diluted share, in 2011. Net income in 2012 included an income tax benefit of $335.8 million, primarily attributable to the release of substantially all of the valuation allowance against our deferred tax assets. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations" below for further details of our financial results.

We currently have three marketed products:

- EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD) and macular edema following central retinal vein occlusion (CRVO). Net product sales of EYLEA in the United States were $1,408.7 million in 2013, $837.9 million in 2012, and $24.8 million in 2011. Bayer HealthCare records revenue from sales of EYLEA outside the United States. EYLEA net product sales outside of the United States commenced in the fourth quarter of 2012, and were $472.1 million in 2013 and $19.0 million in 2012.

  We commenced sales of EYLEA for the treatment of wet AMD in November 2011 and for the treatment of macular edema following CRVO in September 2012, following receipt of regulatory approval in the United States. Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals outside the United States, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD and macular edema secondary to CRVO pending in other countries.

In August 2013, we and Bayer HealthCare announced positive week 52 results from the Phase 3 VISTA-DME and VIVID-DME trials of EYLEA for the treatment of diabetic macular edema (DME), as described below under "Clinical Programs: *EYLEA - Ophthalmologic Diseases.*" Based on the positive results of these studies, we submitted a supplemental Biologics License Application (BLA) for U.S. regulatory approval of EYLEA in DME in the fourth quarter of 2013; the target date for an FDA decision on the supplemental BLA is August 18, 2014. An application for marketing approval for the treatment of DME in the EU was also submitted by Bayer HealthCare during the fourth quarter of 2013. In addition, in February 2014, we and Bayer HealthCare announced positive week 100 results from the Phase 3 VISTA-DME trial, as described below under "Clinical Programs: *EYLEA - Ophthalmologic Diseases.*"

In October 2013, we announced positive week 24 results from the Phase 3 VIBRANT trial of EYLEA for the treatment of macular edema following branch retinal vein occlusion (BRVO), as described below under "Clinical Programs: *EYLEA - Ophthalmologic Diseases.*"

We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare markets, and records revenue from sales of, EYLEA outside the United States, where, for countries other than Japan, the companies share equally the profits and losses from sales of EYLEA. In Japan, we are entitled to receive a percentage of the sales of EYLEA, as described below. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from any such sales.

- ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, known in the scientific literature as VEGF Trap, which is available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. Regulatory applications for marketing authorization of ZALTRAP for the treatment of previously treated mCRC patients in other countries have also been submitted and are currently under review by the respective regulatory agencies. We and Sanofi globally collaborate on the development and commercialization of ZALTRAP, and share profits and losses from commercialization of ZALTRAP, except for Japan, where we are entitled to receive a percentage of the sales of ZALTRAP, as described below. ZALTRAP net product sales, which are recorded by Sanofi, commenced in the United States in August 2012 and in Europe in the first quarter of 2013, and were $70.2 million in 2013 and $31.7 million in 2012.

- ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available 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 are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. Net product sales of ARCALYST totaled $17.1 million in 2013, $20.2 million in 2012, and $19.9 million in 2011.

We have 16 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based clinical programs are:

- EYLEA, which is in clinical trials for the treatment of DME and macular edema following BRVO in collaboration with Bayer HealthCare; and
- ZALTRAP, which is being studied in combination with our angiopoietin-2 inhibitor (nesvacumab) in oncology in collaboration with Sanofi.

Our antibody-based clinical programs include 14 fully human monoclonal antibody product candidates. The following seven are being developed in collaboration with Sanofi:

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and non-infectious uveitis;
- Alirocumab (REGN727), an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- Dupilumab (REGN668), an antibody to the interleukin-4 receptor alpha (IL-4R), which is being developed in atopic dermatitis, asthma, and nasal polyposis;
- Enoticumab (REGN421), an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- Nesvacumab (REGN910), an antibody to angiopoietin-2 (Ang2), another novel angiogenesis target, which is being developed in oncology;
- REGN1033, an antibody to myostatin (GDF8), which is being developed in skeletal muscle disorders; and
- REGN2009, an antibody in clinical development against an undisclosed target.

We are developing the following six antibody product candidates independently:

- REGN1400, an antibody to ErbB3, which is being developed in oncology;
- REGN1154, an antibody in clinical development against an undisclosed target;
- REGN1500, an antibody in clinical development against an undisclosed target;
- REGN1193, an antibody in clinical development against an undisclosed target;
- REGN1908-1909, an antibody combination in clinical development against an undisclosed target; and
- Fasinumab (REGN475), an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain and is currently on clinical hold by the FDA.

In addition, REGN2176-3, a combination product that is comprised of an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta) co-formulated with EYLEA for use in ophthalmology, entered clinical development in the first quarter of 2014, and is being developed in collaboration with Bayer HealthCare.

Development of REGN846, which completed a Phase 1 study against an undisclosed target, was discontinued in the second quarter of 2013.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to combine that foundation with our clinical development, manufacturing, and commercial capabilities. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*® technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

We recently launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC will perform sequencing and genotyping to generate de-identified genomic data. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC intends to pursue both large population-based efforts as well as family-based approaches.

**Clinical Programs:**

***1. EYLEA - Ophthalmologic Diseases***

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 AMD, 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. In CRVO and BRVO, a blockage occurs in the main blood vessel that transports deoxygenated blood away from the retina. VEGF levels are elevated in response, contributing to macular edema. For clinically significant DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision.

EYLEA 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 specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

EYLEA is being evaluated in Phase 3 programs in patients with DME and macular edema following BRVO. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by neovascular proliferation and/or retinal edema.

In August 2013, we and Bayer HealthCare announced that in the Phase 3 VISTA-DME and VIVID-DME trials of EYLEA for the treatment of DME, EYLEA 2 milligrams (mg) dosed monthly and EYLEA 2 mg dosed every two months (after 5 initial monthly injections) achieved the primary endpoint of a significantly greater improvement in best-corrected visual acuity (BCVA) from

baseline compared to laser photocoagulation at 52 weeks. Both EYLEA treatment arms demonstrated similar improvements in BCVA. Based on the positive results of these studies, during the fourth quarter of 2013, we submitted a supplemental BLA for U.S. regulatory approval of EYLEA in DME. the target date for an FDA decision on the supplemental BLA is August 18, 2014. Bayer HealthCare also submitted an application for marketing approval for the treatment of DME in the EU in the fourth quarter of 2013.

We are conducting the VISTA-DME study in the United States. Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. Both of these Phase 3 trials were initiated in the second quarter of 2011, and are similarly designed, randomized, double-masked, active control trials to evaluate the safety and efficacy of EYLEA in patients with DME. Patients in both trials were randomized to receive either EYLEA 2 mg monthly, EYLEA 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation.

In the VISTA-DME trial, after one year patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 12.5 letters ($p<0.0001$ compared to laser) and patients receiving EYLEA 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 10.7 letters ($p<0.0001$ compared to laser), compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 0.2 letters. In the VIVID-DME trial, after one year patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 10.5 letters ($p<0.0001$ compared to laser) and patients receiving EYLEA 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 10.7 letters ($p<0.0001$ compared to laser), compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 1.2 letters.

In addition, in February 2014, we and Bayer HealthCare announced that in the Phase 3 VISTA-DME trial of EYLEA for the treatment of DME, EYLEA 2 mg dosed monthly and EYLEA 2 mg dosed every two months (after 5 initial monthly injections) showed a sustained improvement from baseline in BCVA at week 100, compared to laser photocoagulation. After two years, patients receiving EYLEA 2 mg monthly had a mean change from baseline in BCVA of 11.5 letters and patients receiving EYLEA 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 11.1 letters, compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 0.9 letters.

In these trials, EYLEA was generally well tolerated with a similar overall incidence of adverse events (AEs), ocular serious AEs, and non-ocular serious AEs across the treatment groups and the laser control group. Arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) also occurred at similar rates across the treatment groups and the laser control group. AEs were typical of those seen in other studies in patients with diabetes receiving intravitreal anti-VEGF therapy. The most frequent ocular treatment emergent AEs (TEAEs) observed in the VIVID-DME and VISTA-DME trials included conjunctival hemorrhage, eye pain, and vitreous floaters. The most frequent non-ocular TEAEs included hypertension, nasopharyngitis, anemia, and urinary tract infection, which occurred with similar frequency in the treatment groups and the laser control group.

Full one-year data from the VIVID-DME and VISTA-DME trials were presented at the Retina Society and EURETINA medical conferences in September 2013. Both trials are planned to continue up to 148 weeks. An additional Phase 3 safety study in Japan (VIVID-Japan) was initiated in the first quarter of 2012 and is required for approval in Japan. In February 2013, we and Bayer HealthCare also initiated another Phase 3 study to evaluate the efficacy and safety of EYLEA in DME in Russia, China, and other Asian countries (VIVID EAST-DME).

In the fourth quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial in China evaluating the efficacy and safety of EYLEA in wet AMD (SIGHT). The trial is fully enrolled.

In the second quarter of 2012, we initiated a multinational study (VIBRANT) of EYLEA in patients with macular edema following BRVO. In October 2013, we reported positive, top line results from the VIBRANT trial. In this trial, 53% of patients who received EYLEA 2 mg every four weeks gained at least 15 letters in vision from baseline at week 24, the primary endpoint of the study, compared to 27% of patients who received laser, a standard-of-care treatment ($p<0.001$). Patients who received EYLEA 2 mg every four weeks achieved a 17.0 letter mean improvement over baseline in BCVA compared to a 6.9 letter mean improvement in patients who received laser ($p<0.0001$), a key secondary endpoint. VIBRANT is the first Phase 3 trial in this indication in which an anti-VEGF agent was directly compared to an active comparator. The incidence of serious AEs (SAEs) was 9.9% in the EYLEA group and 9.8% in the laser group. One death and one Anti-Platelet Trialists’ Collaboration (APTC) defined event (non-fatal stroke) occurred during the trial, both in patients in the laser group. The most common ocular adverse events in the EYLEA treated patients were conjunctival hemorrhage and eye pain. There were no cases of intraocular inflammation. There was one ocular SAE in a patient in the EYLEA group, which was a traumatic cataract. The Phase 3 VIBRANT results were presented during the annual meeting of the American Academy of Ophthalmology (AAO) held in November 2013 in New Orleans.

In the fourth quarter of 2012, we initiated a study (RE-VIEW) to fulfill a post-marketing requirement by the FDA, which is evaluating the effect of EYLEA on corneal endothelium. The trial is fully enrolled.

In June 2013, we and Bayer HealthCare announced positive top-line results for EYLEA from the Phase 3 MYRROR study in myopic choroidal neovascularization (mCNV). In this trial, patients receiving EYLEA at an initial dose of 2 mg, followed by treatment on an as-needed (PRN) basis, had a mean improvement in BCVA from baseline at week 24 of 12.1 letters, compared to a loss of 2.0 letters in patients receiving sham injections ($p < 0.0001$). The most common adverse events observed in the MYRROR trial that occurred with a frequency of 2% or more were conjunctival hemorrhage, dry eye, eye pain, headache, and nasopharyngitis. Bayer HealthCare submitted its first application for regulatory approval for this indication in Japan in the fourth quarter of 2013.

***2. ZALTRAP (ziv-aflibercept) - Oncology***

ZALTRAP is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and P1GF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, P1GF) is required for angiogenesis that is needed for tumors to grow.

During the third quarter of 2012, we and Sanofi initiated a Phase 1b study of a combination of ZALTRAP and our angiopoietin-2 inhibitor (nesvacumab) in patients with advanced solid malignancies.

***3. Sarilumab (REGN88; IL-6R Antibody) for inflammatory diseases***

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis (RA), causing inflammation and joint destruction. A therapeutic antibody to IL-6R, ACTEMRA® (tocilizumab), a registered trademark of Chugai Seiyaku Kabushiki Kaisha, has been approved for the treatment of rheumatoid arthritis. Sarilumab is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune* technology.

In the fourth quarter of 2013, we and Sanofi announced that in the SARIL-RA-MOBILITY Phase 3 clinical trial in adult patients with active RA who were inadequate responders to MTX therapy, sarilumab treatment in combination with MTX improved disease signs and symptoms as well as physical function, and inhibited progression of joint damage. The 52 week SARIL-RA-MOBILITY Phase 3 trial enrolled approximately 1,200 patients with active, moderate-to-severe rheumatoid arthritis, and who were inadequate responders to MTX therapy. Patients were randomized to one of three subcutaneous treatment groups, all in combination with MTX and dosed every other week: sarilumab 200 mg, sarilumab 150 mg, or placebo. Both sarilumab groups showed clinically relevant and statistically significant improvements compared to the placebo group in all three co-primary endpoints ($p < 0.0001$).

In the SARIL-RA-MOBILITY trial, there was a higher incidence of treatment emergent adverse events leading to withdrawal in the sarilumab treatment groups compared to placebo (13.9 percent in 200 mg, 12.5 percent in 150 mg and 4.7 percent in placebo). Infections were the most frequently reported adverse events and were reported with a higher incidence in the sarilumab groups compared to placebo, all in combination with MTX (39.6 percent for 200 mg, 40.1 percent for the 150 mg group and 31.1 percent for placebo). The incidence of serious infections was 4.0 percent in the 200 mg + MTX group, 2.6 percent in the 150 mg + MTX group, and 2.3 percent in the placebo + MTX group. Among patients treated with sarilumab, a dose dependent decrease in mean neutrophil counts was observed. Serious infections were not associated with grades 3 and 4 neutropenia in this study. Increases in mean LDL cholesterol, and transaminases were observed. These safety findings were consistent with those observed in prior investigational studies with sarilumab.

Additional analyses of efficacy and safety data from the SARIL-RA-MOBILITY study will be presented at a future medical conference.

We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-TARGET, SARIL-RA-COMPARE, and SARIL-RA- ASCERTAIN. The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe RA who are inadequate responders to either MTX or tumor necrosis factor alpha (TNF-alpha) inhibitor therapy. SARIL-RA-TARGET is a randomized, double-blind, placebo-controlled study evaluating sarilumab in combination with non-biologic, disease-modifying anti-rheumatic drugs (DMARDS) in moderate-to-severe active RA patients with inadequate responses to, or who are intolerant of, one or more TNF-alpha inhibitors. The SARIL-RA-COMPARE study is evaluating the safety and efficacy of sarilumab plus MTX compared to etanercept (a TNF-alpha inhibitor) plus MTX in adult patients with moderate-to-severe RA who demonstrate an inadequate response to adalimumab as their first TNF-alpha inhibitor therapy. The SARIL-RA-ASCERTAIN study is a safety study evaluating the safety and tolerability of sarilumab versus a calibrator, tocilizumab, both in combination with MTX, in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, or SARIL-RA-ASCERTAIN are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.

A Phase 1 study was initiated in the second quarter of 2013 in Japan assessing the safety and tolerability of sarilumab in patients with RA.

In addition, a Phase 2 study, SARIL-NIU-SATURN, was initiated in the fourth quarter of 2013 and is a placebo-controlled proof of concept study evaluating the safety and efficacy of sarilumab in non-infectious uveitis.

***4. Alirocumab (REGN727; PCSK9 Antibody) for LDL cholesterol reduction***

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL through inhibition of HMG-CoA, an enzyme regulating the early and rate-limiting step in cholesterol biosynthesis that ultimately results in an increase in LDL receptors to increase the uptake of plasma LDL lipoproteins. PCSK9 is a secreted protein that plays a key role in modulating LDL cholesterol (LDL-C) levels in the body. PCSK9 binds to and induces the destruction of the LDL receptor, thereby interfering with cellular uptake and increasing circulating levels of LDL cholesterol. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called alirocumab, that is intended to lower LDL cholesterol.

Alirocumab has been studied in three Phase 2 clinical studies, two in patients with primary hypercholesterolemia and one in patients with heterozygous familial hypercholesterolemia (heFH). In the Phase 2 studies, alirocumab significantly reduced LDL-C from baseline up to 72% on top of standard of care statin therapy. Consistent and robust reductions in other lipid parameters, including a reduction in lipoprotein-a (Lp(a)) were also observed. Lp(a) is another form of bad cholesterol which is believed to be a risk factor for coronary heart disease and strokes when elevated. In the Phase 2 program, injection site reactions were the most common adverse events with alirocumab, and were rare. Rare cases of hypersensitivity reaction were also reported. Serious adverse events were reported in 1.8% of patients in the active treatment arms and 2.6% of patients in the placebo groups.

We and Sanofi initiated the global Phase 3 ODYSSEY program for alirocumab in the second quarter of 2012. The ODYSSEY program is expected to enroll more than 23,000 patients. This includes eleven clinical trials evaluating the effect of alirocumab, dosed every two weeks, on lowering LDL cholesterol. In addition, the 18,000 patient ODYSSEY OUTCOMES trial, assessing reduction in serious cardiovascular events, is currently enrolling patients, while the other trials exploring every two week dosing in the ODYSSEY program are fully enrolled. LDL cholesterol reduction is expected to be the primary efficacy endpoint for initial regulatory filings. Also, two trials of alirocumab dosed every four weeks, ODYSSEY CHOICE I and CHOICE II, were initiated in the fourth quarter of 2013 and the first quarter of 2014, respectively. The ODYSSEY studies are being conducted in clinical centers around the world including the United States, Canada, Western and Eastern Europe, South America, Australia, and Asia.

The first trial to report data from the Phase 3 ODYSSEY program was the ODYSSEY MONO trial (in the fourth quarter of 2013), which evaluated the efficacy and safety of alirocumab monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. The study achieved its primary efficacy endpoint and demonstrated that patients randomized to receive alirocumab monotherapy experienced a mean reduction in LDL-C levels of 47.2% from baseline to week 24, compared to 15.6% in patients receiving ezetimibe monotherapy ($p<0.0001$). In the trial, which employed a dose increase (up-titration) for patients who did not achieve an LDL-C level of 70 milligrams/deciliter (mg/dL), the majority of patients remained on the initial low dose of alirocumab of 75 mg. The percentage of patients who reported TEAEs was 78.4% in the ezetimibe group and 69.2% in the alirocumab group. The most common class of AEs was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related AEs occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab.

***5. Dupilumab (REGN668; IL-4R Antibody) for allergic and immune conditions***

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies atopic dermatitis and asthma. Dupilumab is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to bind to IL-4R.

Dupilumab demonstrated positive proof of concept in patients with atopic dermatitis and asthma. Data from two Phase 1b trials in atopic dermatitis were presented at the American Academy of Dermatology annual meeting in March 2013. The efficacy data showed that treatment with four weekly subcutaneous injections of dupilumab at either 150 mg or 300 mg per week, significantly improved the signs and symptoms of patients with moderate-to-severe atopic dermatitis whose disease was not adequately controlled with topical medications. The most common AEs were nasopharyngitis (19.6% vs 12.5% for placebo) and headache (11.8% vs 6.3% for placebo).

Data from a Phase 2a trial in asthma patients with elevated eosinophils were presented at the American Thoracic Society in May 2013, and were also published in the *New England Journal of Medicine* in June 2013. In this study, patients receiving dupilumab at 300 mg weekly for 12 weeks experienced an 87% reduction in the incidence of asthma exacerbations compared to patients receiving placebo ($p<0.0001$). Clinically meaningful and statistically significant improvements were observed for lung function and other asthma control parameters, such as forced expiratory volume over one second ($FEV_1$) (difference from baseline to week 12 between dupilumab and placebo of 0.27 L, $p < 0.001$). TEAEs were reported by a similar proportion of patients in

both groups (76.9% placebo; 80.8% dupilumab). AEs were generally non-specific and of mild-to-moderate intensity. The most common AEs for placebo and dupilumab were injection-site reaction (9.6% and 28.8%), nasopharyngitis (3.8% and 13.5%), upper respiratory tract infection (17.3% and 13.5%), headache (5.8% and 11.5%) and nausea (1.9% and 7.7%).

Data from a 4-week Phase 2 trial in atopic dermatitis were presented at the 22nd Congress of the European Academy of Dermatology and Venereology in October 2013.

In the second quarter of 2013, Phase 2b trials in atopic dermatitis and asthma were initiated. The Phase 2b asthma trial is currently enrolling patients, while the Phase 2b atopic dermatitis trial is fully enrolled. In addition, in the third quarter of 2013, a Phase 2 study in nasal polyposis was initiated and is currently enrolling patients.

***6. Enoticumab (REGN421; Dll4 Antibody) for advanced malignancies***

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

Enoticumab is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune* technology, and is in Phase 1 clinical development.

***7. Nesvacumab (REGN910; Ang2 Antibody) for oncology and ophthalmology***

The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, angiopoietin-2 (Ang2) is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. Enhanced anti-tumor effects have been observed in preclinical models with combined blockade of both VEGF and Ang2.

Nesvacumab is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to block Ang2. Nesvacumab is in Phase 1 clinical development in oncology. In addition, during the third quarter of 2012, we and Sanofi initiated a Phase 1b study evaluating nesvacumab in combination with ZALTRAP in patients with advanced solid malignancies.

In May 2013, we acquired from Sanofi full rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, as described below. We expect to initiate a clinical study for Ang2 in ophthalmology in 2014.

***8. REGN1033 (GDF8 Antibody)***

In the first quarter of 2012, we initiated a Phase 1 clinical study for REGN1033, a fully human monoclonal GDF8 antibody generated using our *VelocImmune* technology. Myostatin has been validated as a target to increase muscle mass and strength through genetic mutations in both animals and humans that abrogate its bioactivity. A Phase 2 program for REGN1033 was initiated in the fourth quarter of 2013.

***9. REGN2009***

REGN2009 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target. In the second quarter of 2013, we initiated a Phase 1 clinical study.

***10. REGN1400 (ErbB3 Antibody) for oncology***

REGN1400 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against ErbB3. In the fourth quarter of 2012, REGN1400 entered into Phase 1 clinical development in oncology.

***11. REGN1154***

REGN1154 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target. Our Phase 1 clinical study in Australia, which was initiated in the first quarter of 2012, has been completed. We are currently evaluating next steps for this program. Sanofi did not opt-in to the REGN1154 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1154.

***12. REGN1500***

REGN1500 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target. In the fourth quarter of 2012, we initiated a Phase 1 clinical study. Sanofi did not opt-in to the REGN1500 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1500.

***13. REGN1193***

REGN1193 is a fully human monoclonal antibody generated using our *VelocImmune* technology, against an undisclosed target. A Phase 1 clinical study of REGN1193 was initiated in the second quarter of 2013. Sanofi did not opt-in to the REGN1193 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1193.

***14. REGN1908-1909***

REGN1908-1909 is a fully human monocolonal antibody combination generated using our *VelocImmune* technology against an undisclosed target. A Phase 1 clinical study of REGN1908-1909 was initiated in the second quarter of 2013. Sanofi did not opt-in to the REGN1908-1909 program and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of REGN1908-1909.

***15. REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA) for ophthalmology***

REGN2176-3 is a combination product comprised of an antibody to PDGFR-beta, which was generated using our *VelocImmune* technology, co-formulated with EYLEA for use in ophthalmology. In February 2014, we initiated a Phase 1 clinical study of REGN2176-3 for the treatment of wet AMD.

In May 2013, we acquired from Sanofi full rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology, as described below.

In January 2014, we and Bayer HealthCare entered into an agreement regarding the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination therapy with EYLEA, for the treatment of ocular diseases or disorders (including wet AMD) as described further in the "Collaborations with Bayer HealthCare" section below.

***16. Fasinumab (REGN475; NGF Antibody) for pain (on clinical hold)***

Fasinumab is a fully human monoclonal antibody to NGF, generated using our *VelocImmune* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that fasinumab specifically binds to and blocks NGF activity and does not bind to or block cell signaling for the closely related neurotrophins NT-3 and BDNF.

In December 2012, the FDA placed fasinumab and other investigational agents targeting NGF on clinical hold based on preclinical findings with other anti-NGF agents in development. Prior to the FDA clinical hold action, we were planning to initiate late-stage clinical trials with fasinumab. There are currently no ongoing trials with fasinumab that are either enrolling or treating patients.

Sanofi elected not to continue co-development of fasinumab, and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of fasinumab.

**Acquisition of Ophthalmology Development Programs from Sanofi**

In May 2013, we acquired from Sanofi full exclusive rights to two families of novel antibodies invented at Regeneron and previously included in our antibody collaboration with Sanofi. We acquired full rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology.

With respect to PDGF antibodies, we made a $10.0 million up-front payment to Sanofi in May 2013, a $5.0 million development milestone payment to Sanofi in January 2014, and are obligated to pay up to $35 million in additional potential development milestones and royalties on any future sales. With respect to Ang2 antibodies in ophthalmology, we also made a $10.0 million up-front payment to Sanofi in May 2013, and are obligated to pay a potential $5 million development milestone payment and royalties on any future sales.

We and Sanofi have agreed to continue to develop antibodies to Ang2 outside of ophthalmology under our antibody collaboration agreement, including nesvacumab, as described above.

**Research Programs**

Our preclinical research programs are in the areas of oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

**Research and Development Technologies**

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our three approved products, EYLEA, ZALTRAP, and ARCALYST. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region," resulting in high affinity product candidates. *VelociSuite* is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

***VelociSuite.*** *VelociSuite* consists of *VelocImmune*, *VelociGene*, *VelociMouse®, and VelociMab*. The *VelocImmune* mouse platform is utilized to produce fully human monoclonal antibodies. *VelocImmune* was generated by exploiting our *VelociGene* technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

We have utilized our *VelociSuite* technologies to develop a class of potential drug candidates, known as bi-specific antibodies. In the area of immunotherapies in oncology, we are exploring the use of bi-specific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. Our first such bi-specific antibody, which we expect to advance into clinical development later in 2014, targets CD20 and CD3.

***Regeneron Genetics Center (RGC).*** We recently launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC intends to pursue both large population-based efforts as well as family-based approaches.

Central to the work of RGC will be a collaboration with the Geisinger Health System of Pennsylvania. During the initial five-year collaboration term, Geisinger plans to collect samples from more than 100,000 consented patient volunteers, while RGC will perform sequencing and genotyping to generate de-identified genomic data.

**Collaboration Agreements**

**Collaborations with Sanofi**

***ZALTRAP.*** Since September 2003, we and Sanofi have been parties to a global collaboration for the development and commercialization of ZALTRAP. Under the current terms of our collaboration agreement we and Sanofi share co-promotion rights and share profits and losses from commercialization of ZALTRAP outside of Japan. In Japan, we are entitled to receive a percentage of approximately 35% on sales of ZALTRAP, subject to certain potential adjustments.

Under the collaboration agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi out of our share of ZALTRAP profits for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAP profits in the quarter unless we elect to reimburse Sanofi at a faster rate. As a result, we expect that, initially, our share of any ZALTRAP profits will be used to reimburse Sanofi for this repayment obligation.

***Antibodies.*** Since November 2007, we and Sanofi have been parties to 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 (each as amended). Pursuant to the collaboration, Sanofi is funding up to $160 million per year of our antibody discovery activities over the period from 2010-2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an IND or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified through discovery research under the discovery agreement, Sanofi has the option to license rights to the candidate under the license agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

Sanofi will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. We and Sanofi will equally share profits and losses from sales within the United States. We and Sanofi will share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and will share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

**Collaborations with Bayer HealthCare**

***EYLEA outside the United States.*** Since October 2006, we and Bayer HealthCare have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of EYLEA through an integrated global plan. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In May 2012, Bayer HealthCare's Japanese subsidiary, Bayer Yakuhin, Ltd., and Santen Pharmaceutical Co., Ltd. entered into an agreement to co-promote EYLEA in Japan. In conjunction with this agreement, we and Bayer HealthCare amended our existing global license and collaboration agreement for EYLEA to convert the 50/50 profit share for Japan into an agreement under which we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA annual net sales in Japan. In certain specified circumstances, the Japan arrangement may revert to a profit share arrangement.

To date, we have received $110.0 million of development milestone payments and $45.0 million of sales milestone payments from Bayer HealthCare. In addition, we may earn up to $120 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became 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 (including payments to us based on sales in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. As a result, we expect that, initially, a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer HealthCare for this repayment obligation.

Within the United States, we retain exclusive commercialization rights to EYLEA and are entitled to all profits from any such sales.

***PDGFR-beta antibody outside the United States.*** In January 2014, we entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to the collaboration for further development and commercialization outside the United States.

In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made a $2.5 million payment to us in January 2014. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to $17.5 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

If Bayer HealthCare exercises their right to opt-in to the collaboration, they will obtain exclusive commercialization rights to the product outside the United States, pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a $20 million opt-in payment to us, pay a $20 million development milestone to us upon receipt of the first marketing approval in the European Union or Japan, share profits from sales outside the United States equally with us, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. If Bayer HealthCare does not opt-in to the collaboration, we will have exclusive rights to develop and commercialize PDGFR-beta antibodies (except as a combination product with EYLEA) for use outside the United States.

We also have the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If we opt-out of the collaboration and Bayer HealthCare exercises their right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing a PDGFR-beta antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both us and Bayer HealthCare in writing.

Under the agreement, Bayer HealthCare has also agreed to a “standstill” provision, which prohibits Bayer HealthCare and its affiliates from seeking to influence the control of our company or acquiring more than 20% of our then outstanding shares of Class A Stock and Common Stock (taken together). For further information regarding this provision, see Part I, Item 1A. “Risk Factors - *The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements and our convertible senior notes and related warrant and hedge transactions, could deter, delay, or prevent an acquisition or other “change in control” of us and could adversely affect the price of our Common Stock.”*

**Manufacturing**

Our manufacturing facilities are located in Rensselaer, New York and currently consist of three buildings totaling approximately 425,000 square feet of research, manufacturing, office, and warehouse space. We currently have approximately 54,000 liters of cell culture capacity at these facilities. A current expansion project will add 20,000 liters of cell culture capacity and 65,000 additional square feet of space once construction is completed, which is expected by 2015. At December 31, 2013, we employed approximately 750 people at our Rensselaer facilities. We also depend on a limited number of third party providers for other services with respect to our clinical and commercial product supply requirements, including product packaging, filling, and labeling.

In July 2013, we reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick. We intend to renovate this facility to accommodate and support our growth, primarily in connection with expanding our bulk manufacturing capacity to support our global supply chain.

Certain raw materials or other products necessary for the manufacture and formulation of EYLEA, ZALTRAP, 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, laboratory testing, and other services related to the manufacture of EYLEA, ZALTRAP, ARCALYST, and our product candidates, and to supply various raw materials and other products. See Part I, Item 1A. “Risk Factors - Risks Related to Manufacturing and Supply” for further information.

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. We are approved to manufacture our marketed products at our Rensselaer facilities.

**Sales and Marketing**

We have a New Products Marketing and Planning group and a Market Research group to evaluate commercial opportunities for our targets and drug candidates, assess the competitive environment, and analyze the commercial potential of our product portfolio, and prepare for market launch of new products. This group works in close collaboration with our collaborators for co-developed products to develop marketing plans and forecasts and to develop and execute pre-launch market development programs.

We also have a full-service commercialization group to handle various aspects of our EYLEA program. The group includes experienced professionals in the fields of marketing, communications, professional education, patient education and advocacy, reimbursement and managed markets, trade and distribution, commercial operations, commercial analytics, market research, and forecasting. Moreover, we have hired, trained, and deployed a field-based organization including regional sales directors, medical sales specialists, and reimbursement managers, each typically with 7 or more years of experience in the biopharmaceutical industry in a variety of therapeutic areas including oncology, ophthalmology, immunology, and inflammation. We outsource the warehousing and distribution of our finished drug products.

In connection with the sales and marketing of ARCALYST for CAPS, we have a marketing, trade, reimbursement, and distribution group to provide case management and reimbursement services to patients with CAPS and their treating physicians.

In connection with the U.S. marketing of ZALTRAP, we have a marketing and market access group to work in collaboration with Sanofi.

**Customers**

We sell EYLEA in the United States to three distributors and several specialty pharmacies. We sell ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers, whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. For the years ended December 31, 2013, 2012, and 2011, we recorded 76%, 78%, and 42%, respectively, of our total gross product revenue from sales to a single distributor, Besse Medical, which is a subsidiary of AmerisourceBergen Corporation.

**Competition**

We face substantial competition from pharmaceutical, biotechnology, and chemical companies. Our competitors include Genentech (a member of the Roche Group), Roche, Novartis AG, Pfizer Inc., Bayer HealthCare, Allergan, Inc., Eli Lilly and Company, AbbVie Inc., Sanofi, Merck & Co., Inc., Amgen Inc., AstraZeneca PLC, Bristol-Myers Squibb Company, Johnson & Johnson, GlaxoSmithKline plc, 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 if we are able to commercialize additional product candidates, one or more of our competitors may have brought a competitive product to market earlier than us or may have obtained or obtain patent protection that dominates or adversely affects our activities or products. Our ability to compete depends, to a great extent, 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 is based on efficacy, safety, reliability, availability, price, patent position, and other factors.

*EYLEA.* The following table provides an overview of the competitive landscape for EYLEA:

| Competitor Product/Product Candidate | Commercial or Development Status | Competitor | Indication | Territory |
|---|---|---|---|---|
| Lucentis® | Approved | Novartis/Genentech | Wet AMD, DME, macular edema following RVO, choroidal neovascularization secondary to pathologic myopia, and other eye indications | Worldwide |
| Avastin® (off-label) | Used to treat wet AMD, DME, and macular edema following RVO | Genentech | Wet AMD, DME, and macular edema following RVO | Sold worldwide<br><br>Being evaluated in trials in the United Kingdom, Canada, Brazil, Germany, and other countries |
| Conbercept | Approved in China for wet AMD<br><br>In development for other eye indications | Chengdu Kanghong Pharmaceutical Group | Wet AMD | China |
| Fovista™, an aptamer directed against PDGF-B | In development (Phase 3 trials initiated in 2013 evaluating multiple combinations of Fovista™, including Lucentis® + Fovista™, Avastin® + Fovista™, and EYLEA + Fovista™) | Ophthotech Corporation | Wet AMD | — |
| ESBA1008, a single chain antibody fragment directed against VEGF-A | In development (Phase 2 trial initiated in 2013 comparing ESBA1008 and EYLEA) | Novartis | Wet AMD | — |
| Anti-VEGF-A-DARPin® | In development (Phase 2) | Allergan | Wet AMD and related conditions | — |
| Bi-specific antibody R06867461 | In development (Phase 1) | Genentech | Wet AMD | — |
| Lucentis® Sustained Delivery System | In development (Phase 1) | Genentech | Wet AMD and related conditions | |

The table above is not exhaustive. For additional information regarding the substantial competition EYLEA faces, see Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of EYLEA - *The commercial success of EYLEA is subject to strong*

*competition*" and Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Products - *Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition.*"

*ZALTRAP.* The following table provides an overview of the competitive landscape for ZALTRAP:

| Competitor Product/Product Candidate | Commercial or Development Status | Competitor | Indication | Territory |
|---|---|---|---|---|
| Avastin® | Approved and launched in 2004 | Genentech | Certain cancers | Worldwide |
| Oral medications that target tumor cell growth and new vasculature formation that fuels growth of tumors | Being sold and marketed | Pfizer, Amgen (together with its partner Bayer HealthCare), GlaxoSmithKline, and Bayer HealthCare | Certain cancers | Worldwide |
| Other VEGF antagonists | In various phases of development | Novartis, Amgen, Imclone LLC/Eli Lilly, Pfizer, AstraZeneca, GlaxoSmithKline, and Aveo | Certain cancers | — |

The table above is not exhaustive. For additional information regarding the substantial competition ZALTRAP faces, see Item 1A. "Risk Factors - Risks Related to Commercialization of Products - *Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition.*"

*Monoclonal Antibodies.* Our clinical candidates in development are all fully human monoclonal antibodies which were generated using our *VelocImmune* technology. Our antibody generation technologies and clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies. Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Inc., Novartis, Genentech, Bristol-Myers Squibb, AbbVie, 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. Astellas has licensed our *VelocImmune* technology as part of their internal antibody development programs.

The following table provides an overview of the competitive landscape for our antibody programs that are in late-stage clinical development.

| Regeneron Antibody Program | Competitor | Competitor Product/Product Candidate | Commercial or Development Status | Target |
|---|---|---|---|---|
| Alirocumab (Phase 3)<br>Target: PCSK9 | Amgen | Evolocumab (AMG-145) | In development (Phase 3) | Antibody against PCSK9 |
| | Pfizer | Bococizumab (RN316 / PF-04950615 | In development (Phase 3) | Antibody against PCSK9 |
| | Genentech | RG7652 | In development (Phase 2) | Antibody against PCSK9 |
| | Eli Lilly | LY3015014 | In development (Phase 2) | Antibody against PCSK9 |
| | Bristol-Myers Squibb | BMS-962476 | In development (Phase 1) | Adnectin against PCSK9 |
| | Alnylam (in partnership with The Medicines Company) | ALN-PCS | In development | RNAi against PCSK9 |

| Regeneron Antibody Program | Competitor | Competitor Product/Product Candidate | Commercial or Development Status | Target |
|---|---|---|---|---|
| Sarilumab (Phase 3)<br>Target: IL-6R | Roche | Tocilizumab (Actemra®) | Approved | Antibody against IL-6R for the treatment of rheumatoid arthritis and systemic juvenile idiopathic arthritis |
| | Johnson & Johnson (in partnership with GlaxoSmithKline) | Sirukumab | In development (Phase 3) | Antibody against IL-6 |
| | Bristol-Myers Squibb (in partnership with Alder Biopharmaceuticals, Inc.) | Clazakizumab | In development (Phase 2) | Antibody against IL-6 |
| | Ablynx (in partnership with AbbVie) | ALX-0061 | In development (Phase 2) | Antibody against IL-6R |
| | R-Pharm | Olokizumab | In development (Phase 2) | Antibody against IL-6 |
| | Pfizer | PF-04236921 | In development (Phase 1) | Antibody against IL-6 |
| | Roche | SA 237 | In development (Phase 1) | Antibody against IL-6R |
| Dupilumab (Phase 2)<br>Target: IL-4R | Roche | Lebrikizumab | In development (Phase 3) | Antibody against IL-13 |
| | Teva | Reslizumab | In development (Phase 3) | Antibody against IL-5 |
| | GlaxoSmithKline | Mepolizumab | In development (Phase 3) | Antibody against IL-5 |
| | AstraZeneca | Benralizumab | In development (Phase 3) | Antibody against IL-5R |
| | AstraZeneca | Tralokinumab | In development (Phase 2) | Antibody against IL-13 |
| | Novartis | QBX258 | In development (Phase 2) | Fixed dose combination of antibodies against IL-4 and IL-13 |
| | GlaxoSmithKline | GSK2434735 | In development (Phase 1) | Bi-specific antibody against IL-4 and IL-13 |

The table above is not exhaustive. For additional information regarding our antibody programs and the substantial competition they face, see "Clinical Programs" above and Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Products - *Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition*."

*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. 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 any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business, operating results, financial condition, cash flows, or future prospects.

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.

**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 Part I, Item 1A. “Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - *We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, patents or other proprietary rights of others.*”). 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, 2013, we held an ownership interest in a total of approximately 233 issued patents in the United States and approximately 1,162 issued patents in foreign countries with respect to our products and technologies. In addition, we hold 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 2028. 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 products, EYLEA, ZALTRAP, and ARCALYST, and our product candidates in clinical development. These patents cover the proteins and DNA encoding the proteins, manufacturing patents, method of use patents, and pharmaceutical compositions, as well as various methods of using the products. For each of EYLEA, ZALTRAP, and ARCALYST, these patents generally expire between 2020 and 2028. 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 December 2011, we and Genentech entered into a Non-Exclusive License and Partial Settlement Agreement relating to ophthalmic sales of EYLEA in the United States. Pursuant to this agreement, we received a non-exclusive license to certain patents relating to VEGF receptor proteins, known as the Davis-Smyth patents, and other technology patents. In May 2013, we entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech; under the amended agreement, we received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of human eye diseases and eye disorders through administration of EYLEA to the eye. Also in May 2013, we entered into a Non-Exclusive License and Settlement Agreement with Genentech and Sanofi under which we and Sanofi received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than the prevention or treatment of eye diseases and eye disorders through administration to the eye.

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.

We also have non-exclusive license agreements with Amgen and other organizations for patent rights related to 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 (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - *We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, patents or other proprietary rights of others.*").

**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 EYLEA, ZALTRAP, ARCALYST, and our product candidates (see Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of EYLEA - *Our regulatory approval for sales of EYLEA is limited to the treatment of wet AMD and macular edema following CRVO and is limited geographically. If we don't receive approval for EYLEA for other indications, or if approvals are not obtained for sales in other countries, our sales and profits will be limited* and Risks Related to the Development and Approval of Our Product Candidates and New Indications for Our Marketed Products - *If we do not obtain and maintain regulatory approval for our products and product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.")*. 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 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 IND, 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 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 includes revenues and expenses related to (i) product sales of EYLEA and ARCALYST, (ii) research and development activities conducted under our collaboration agreements with third parties, (iii) our share of the income (loss) from commercialization of products under our collaboration agreements, (iv) licensing agreements to utilize our *VelocImmune* technology, and (v) the supply of specified, ordered research materials using our *VelociGen*e technology platform.

**Employees**

As of December 31, 2013, we had approximately 2,340 full-time employees, of whom approximately 410 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.

**Corporate Information**

We were incorporated in the State of New York in 1988 and publicly listed in 1991. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number at that address is (914) 847-7000.

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 Securities and Exchange Commission (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, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

**Risks Related to Commercialization of EYLEA**

***We are substantially dependent on the success of EYLEA. If we are unable to continue to commercialize EYLEA or if we are unable to obtain additional marketing approvals, our business, prospects, operating results, and financial condition will be materially harmed.***

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the years ended December 31, 2013 and 2012, EYLEA net sales in the United States represented 67% and 61% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer HealthCare were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer HealthCare are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed. In addition, if we are unable to obtain approval of EYLEA in the United States for the treatment of DME, or if Bayer HealthCare is unable to obtain approval of EYLEA in additional countries or in additional indications, our prospects would be materially harmed.

***We are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we fail to maintain regulatory compliance for EYLEA, we may lose marketing approval, which would materially harm our business, prospects, operating results, and financial condition.***

EYLEA is currently available in the United States, EU, Japan, and certain other countries outside of the United States for treatment of wet AMD and macular edema following CRVO. We are subject to significant ongoing regulatory obligations with respect to EYLEA for the treatment of wet AMD and macular edema following CRVO in the United States and the EU, and, in other countries, the commercialization of EYLEA is subject to additional significant ongoing regulatory obligations and oversight in those countries where the product is approved. If we fail to maintain regulatory compliance for EYLEA for the treatment of wet AMD and macular edema following CRVO, we may lose marketing approval, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply—*If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales*" below.

***Serious complications or side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition.***

There are risks inherent in intravitreal injections, including intravitreal injections with EYLEA, such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and other side effects, all of which are reported from time to time to the FDA. Serious complications or serious, unexpected side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition.

***Our regulatory approval for sales of EYLEA is limited to the treatment of wet AMD and macular edema following CRVO and is limited geographically. If we don't receive approval for EYLEA for other indications, or if approvals are not obtained for sales in other countries, sales and profits will be limited.***

We and Bayer HealthCare have received regulatory approvals for sale of EYLEA for the treatment of wet AMD and macular edema following CRVO in certain countries throughout the world. If we do not receive approval for EYLEA for other uses, or if approvals for sales in other countries are not obtained, sales will be limited and our potential for profits will be limited. As a result, our business, prospects, operating results, and financial condition would be materially impacted.

***Our sales of EYLEA are dependent on the availability and extent of reimbursement from third-party payers, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.***

Our sales in the United States of EYLEA are dependent, in part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of EYLEA. Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products—*The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not agree to cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

***The commercial success of EYLEA is subject to strong competition.***

The market for eye disease products is very competitive, as summarized under Part I, Item 1. “Business - Competition - *EYLEA*” above. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis®, for the treatment of wet AMD, macular edema following CRVO, DME, visual impairment due to mCNV, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD, in June 2010 for the treatment of macular edema following RVO (including CRVO and BRVO), and in August 2012 for the treatment of DME. Lucentis® was also approved by the European Medicines Agency for wet AMD in January 2007, for DME in January 2011, for the treatment of macular edema following RVO (including CRVO and BRVO) in June 2011, and for mCNV in July 2013. Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME and RVO including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, in January 2012, Genentech submitted an IND for such an extended delivery device. Novartis is developing ESBA1008, a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated Phase 2 trials comparing ESBA1008 and EYLEA in 2013. Allergan is developing an anti-VEGF-A DARPin® for wet AMD and related conditions and a Phase 2 trial is ongoing. Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, PDGF). Ophthotech Corporation is developing Fovista™, an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In 2013, Ophthotech initiated Phase 3 trials in AMD evaluating multiple combinations of Fovista™, including Lucentis® + Fovista™, Avastin® + Fovista™, and EYLEA + Fovista™. Genentech initiated a Phase 1 trial of a bi-specific antibody for wet AMD.

In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech's approved VEGF antagonist, Avastin®, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. Long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD are being conducted. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT) were reported in April 2011 and indicated that Avastin® dosed monthly was non-inferior to Lucentis® dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Two-year data from CATT were reported in April 2012 and indicated that monthly Avastin® was non-inferior to monthly Lucentis® in mean visual acuity gain; as-needed dosing was *not* non-inferior to monthly dosing. Avastin® is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other countries. Furthermore, Lucentis® and off-label use of Avastin® present significant competitive challenges as doctors and patients have had significant experience using these medicines. Moreover, the reported results of the CATT study, combined with the relatively low cost of Avastin® in treating patients with wet AMD, may well exacerbate the competitive challenge which EYLEA faces in this or other eye indications for which it may be approved. Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, and while we believe that ZALTRAP would not be well tolerated if administered directly to the eye, there is a risk that third parties may attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for wet AMD, macular edema following CRVO, or other eye indications. See also “Risks Related to Commercialization of Products—*We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects*” below.

***Our product sales could be reduced by imports from countries where our products are available at lower prices.***

Our sales of products in the United States may be reduced if our products are imported into the United States from lower priced markets, whether legally or illegally. Under our arrangement with Bayer HealthCare, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer HealthCare. Prices for EYLEA in territories outside the United States will be based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and our sales of EYLEA in the United States may be reduced if EYLEA is marketed in those nations and imported into the United States. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues could be reduced.

**Risks Related to the Development and Approval of Our Product Candidates and New Indications for Our Marketed Products**

***If we do not obtain and maintain regulatory approval for our products and product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.***

We cannot sell or market products without regulatory approval. If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates, or new indications of our marketed products, including EYLEA for the treatment of ophthalmologic diseases other than wet AMD and macular edema following CRVO, the value of our company and our business, prospects, operating results, and financial condition will be materially harmed. Our product candidates, including EYLEA for DME and macular edema following BRVO, may not receive regulatory approval. If we are unable to obtain regulatory approval for EYLEA in DME and macular edema following BRVO, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition will be materially harmed. In addition, if we fail to maintain regulatory approval for EYLEA for the treatment of wet AMD and macular edema following CRVO, we may lose marketing approval and the ability to generate EYLEA product sales revenue, which would materially and negatively impact our business, prospects, operating results, and financial condition.

***Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.***

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is similarly likely to be a lengthy and expensive process, and approval is highly uncertain.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, prospects, operating results, and financial condition 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 and requirements include all of the risks associated with FDA approval as well as country specific regulations, and actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

***Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.***

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies 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 a clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to Good Laboratory Practices (GLPs) or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

***Successful development of our current and future product candidates is uncertain.***

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. For example, a randomized, double-blind Phase 3 trial (VENICE) that evaluated ZALTRAP as a first-line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone did not meet the pre-specified criterion of improvement in overall survival in April 2011. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP as a first-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in 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 product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical “pipeline” and could negatively affect our future prospects and the value of our company.

***Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.***

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 and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

EYLEA is being studied in diseases of the eye in addition to wet AMD and macular edema following CRVO. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize EYLEA and ZALTRAP. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including ZALTRAP delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like EYLEA, which can cause injury to the eye and other complications. For example, in our Phase 3 trials of EYLEA in wet AMD, the most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. These and other complications or side effects could harm the development and/or commercialization of EYLEA or ZALTRAP.

We and Sanofi are conducting a global development program, currently in Phase 3, studying alirocumab, our PCSK9 antibody for the reduction of LDL cholesterol, as discussed above in Part I, Item 1. "Business - Clinical Programs." As part of this development program, we and Sanofi collect adverse events and report them to the FDA and foreign regulatory authorities. In the Phase 2 program, injection site reactions were the most common adverse events with alirocumab, and were rare. Rare cases of hypersensitivity reaction were also reported. In a recent Phase 3 trial comparing alirocumab with ezetimibe, the most common class of adverse events was infections (39.2% with ezetimibe vs. 42.3% with alirocumab), which included nasopharyngitis, influenza, and upper respiratory tract infection. Injection-site reactions occurred in less than 2% of patients in both groups. Muscle-related adverse events occurred in 3.9% of patients treated with ezetimibe and 3.8% of patients treated with alirocumab. We and Sanofi have been advised by the FDA that it has become aware of neurocognitive adverse events in the PCSK9 inhibitor class. Neurocognitive adverse events have also been associated with the use of statins for lowering LDL cholesterol. We do not know the circumstances under which the FDA became aware of these adverse events or whether these adverse events were observed with a drug candidate tested as monotherapy or in combination with a statin or other cholesterol-lowering agent. The FDA has requested that we and Sanofi make an assessment of potential neurocognitive adverse events across the global development program for alirocumab, especially in the longer-term studies. Additionally, the FDA requested that we address the feasibility of incorporating neurocognitive testing into at least a subset of patients in our ODYSSEY OUTCOMES trial or other long-term Phase 3 trial(s). While we are not aware of any neurocognitive adverse event signal relating to alirocumab, if this or another adverse event signal is detected, the further development of alirocumab may be delayed or fail, or its commercial value diminished, which could severely harm our future prospects.

We have studied fasinumab in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the FDA placed fasinumab and other investigational agents targeting NGF on clinical hold after a case of rapidly progressive osteoarthritis leading to joint replacement was seen in another company's anti-NGF program due to the FDA's concern that this case was suggestive of a class effect. In December 2012, the FDA removed the clinical hold on fasinumab after reviewing our proposed Phase 3 program in osteoarthritis. However, shortly thereafter, the entire class was again placed on clinical hold as a result of preclinical data from other investigational agents targeting NGF in development. There are currently no trials with fasinumab that are either enrolling or treating patients. Discussions with the FDA about fasinumab are ongoing.

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

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

***We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.***

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

**Risks Related to Intellectual Property and Market Exclusivity**

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our own employees, our collaborators or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. We have pending patent applications in the United States Patent and Trademark Office, the European Patent Office, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patent applications from challenges by others from time to time in the future. Certain patent applications filed in the United States may also be challenged by parties who file a request for post-grant review under the America Invents Act of 2011. We expect that post-grant review proceedings will become common in the United States and will be costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune* technology, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation. For example, we are currently parties to patent infringement proceedings relating to our European Patent No. 1,360,287, which concerns genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part I, Item 3. "Legal Proceedings." We are aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R and PCSK9 and methods of treating rheumatoid arthritis and hypercholesterolemia with such antibodies. We are developing sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis, and alirocumab, a PCSK9 antibody, for LDL cholesterol reduction. Although we do not believe that sarilumab or alirocumab infringes any valid claim in these patents or patent applications, these other parties could initiate a lawsuit for patent infringement and assert their patents are valid and cover sarilumab or alirocumab, as applicable. We are also aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and

may choose to produce additional antibody product candidates in this manner. Neither ARCALYST, ZALTRAP, nor EYLEA are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to make recombinant antibodies in, or to import them into, the United States. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our drug candidates, or our other late-stage product candidates, infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

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

***Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.***

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "*If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed*," the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, there is now a new, abbreviated path in the United States for regulatory approval of biosimilar versions of biological products. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this new regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

**Risks Related to Manufacturing and Supply**

***We rely on limited internal and contracted manufacturing and supply chain capacity, which could result in our being unable to continue to successfully commercialize EYLEA, to commercialize our other product candidates or other indications for our marketed products if they receive regulatory approval, and to advance our clinical pipeline.***

Our manufacturing facility would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA, ZALTRAP, and ARCALYST, and (b) our antibody product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody product candidates, our current manufacturing capacity may not be sufficient, and we may depend on our collaborators or contract manufacturers, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

***Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and late-stage product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.***

We have commenced construction of additional manufacturing space at our Rensselaer, New York site to increase our manufacturing capacity. In addition, we reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick, to expand our manufacturing capacity to support our global supply chain. In the future, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing activities. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. In addition, our contemplated acquisition of the Limerick, Ireland facility remains subject to entering into definitive agreements as well as securing permits from the local government, and there is no guarantee that a final agreement will be reached on terms favorable to us or that we will be able to obtain the required permits in the contemplated timeframe, or at all. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize EYLEA, ZALTRAP, and ARCALYST and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

***Our ability to manufacture our products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.***

Our ability to continue to manufacture EYLEA, ZALTRAP, and ARCALYST in our Rensselaer, New York facilities and, in the future, our ability to manufacture our marketed products at additional facilities, or to utilize third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products to which those intellectual property rights apply, which could materially harm our business, prospects, operating results, and financial condition.

***If sales of EYLEA and ZALTRAP do not meet the levels currently expected, or if the launch of new indications for EYLEA or of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties.***

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product of EYLEA for the treatment of wet AMD and macular edema following CRVO, bulk product of ZALTRAP for the treatment of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, bulk product of ARCALYST for the treatment of CAPS, and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

***Third-party service or supply failures, or other failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.***

We currently manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, acts of war or terrorism, or other problems at the facilities.

Also, certain raw materials or other products necessary for the manufacture and formulation of EYLEA, ZALTRAP, ARCALYST, and our product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of EYLEA, ZALTRAP, ARCALYST, and our product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, 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 actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply EYLEA, ZALTRAP, ARCALYST, and our product candidates, which could materially and adversely affect our business and future prospects.

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

***If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.***

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and

product candidates at our facility in Rensselaer, New York, including EYLEA, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

**Risks Related to Commercialization of Products**

***We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.***

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture, market and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

Currently, we have three marketed products, EYLEA, ZALTRAP, and ARCALYST. While we have established our own sales and marketing organization for EYLEA in the United States for the treatment of wet AMD and macular edema following CRVO, we have limited commercialization experience and we have no sales, marketing, commercial, or distribution capabilities outside the United States. In addition, EYLEA faces intense competition from Lucentis® and from off-label use of repackaged Avastin®, both of which have been on the market for a number of years and, potentially, from new competitive products currently in clinical development. We expect that the continued commercial success of EYLEA will depend on many factors, including the following:

- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA as compared to the dosing regimen of Lucentis®, and the willingness of retinal specialists and patients to switch from Lucentis® or off-label use of Avastin® to EYLEA;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development; and
- the effect of new health care legislation currently being implemented in the United States.

Under the terms of our license and collaboration agreement with Bayer HealthCare, we rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA in countries outside the United States. If we and Bayer HealthCare are unsuccessful in

continuing to commercialize EYLEA, our ability to sustain profitability would be materially impaired. In addition, if we or our collaborators are unable to successfully commercialize new product candidates or new indications for our marketed product, our future prospects would be materially impaired.

***Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition.***

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies, as summarized under Part I, Item 1. “Business - Competition” above. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as 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 commercialization of our product candidates, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

As previously noted, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers, and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen Inc., Imclone LLC/Eli Lilly, Pfizer Inc., AstraZeneca, and GlaxoSmithKline. Some of these molecules may offer competitive advantages over our molecule. Each of Pfizer, Onyx (recently acquired by Amgen), together with its partner Bayer HealthCare, and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. In January 2012, Roche announced that a Phase 3 trial of Avastin® (bevacizumab) had met the primary endpoint of overall survival in mCRC in patients who had previously received Avastin® with standard chemotherapy. The positive results of this trial in a similar patient population could impact the potential commercial opportunity for ZALTRAP in mCRC. It will be difficult for ZALTRAP to compete against Avastin® and the FDA-approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is very competitive, as described in greater detail above under “Risks Related to Commercialization of EYLEA-*The commercial success of EYLEA is subject to strong competition*.”

Our earlier stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune* technology. Our antibody generation technologies and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

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 (in partnership with Eli Lilly), Johnson & Johnson, and AbbVie are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), Bristol-Myers Squibb (in partnership with Alder Biopharmaceuticals), Ablynx (in partnership with AbbVie), and Pfizer have antibodies against IL-6 or IL-6R in clinical development. Several companies, including Amgen, Pfizer, Genentech, Bristol-Myers Squibb, and Eli Lilly, have development programs for antibodies against PCSK9. Amgen's PCSK9 program appears to be the most advanced of the competitors, having already announced positive results from multiple Phase 3 trials, and may obtain marketing approval in one or more countries before our PCSK9 antibody is approved. Alnylam, in partnership with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action currently on the market or in development, including oral products and a biosimilar product in Europe. Further, Amgen, Genentech, and AstraZeneca have development programs underway for antibodies against Ang2 for indications in oncology. Celgene (in partnership with OncoMed Pharmaceuticals, Inc.) and AstraZeneca have antibodies that target Dll4 in clinical development. For muscle-wasting conditions, both Pfizer and Eli Lilly have anti-GDF8 monoclonal antibodies in development, and Novartis has a competing antibody targeting ActRIIB.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

***The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not agree to cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition.***

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

Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by CMS and other federal and state agencies. Further, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled “Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration” in which the OIG details possible savings to the Medicare program by using off-label Avastin® rather than Lucentis® for the treatment of wet AMD. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since EYLEA for the treatment of wet AMD, macular edema following CRVO, and other eye diseases, and ZALTRAP for the treatment of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, will likely continue to be too expensive for most patients to afford without health insurance coverage, if these products are unable to obtain adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, our ability to successfully commercialize these products would be materially adversely impacted. Third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse for these products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

***We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.***

We sell EYLEA in the United States to three distributors and several specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the years ended December 31, 2013, 2012, and 2011, we recorded 76%, 78%, and 42%, respectively, of our total gross product revenue from sales to a single distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

**Regulatory and Litigation Risks**

***If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.***

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

***If we market and sell approved products in a way that violates federal or state healthcare laws, we may be subject to civil or criminal penalties.***

In addition to FDA and related regulatory requirements, we are subject to health care “fraud and abuse” laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and 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 challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the PPACA, the federal government recently enacted the Physician Payment Sunshine Act and related regulations. The Physician Payment Sunshine Act will require pharmaceutical manufacturers to report annually to the Secretary of the U.S. Department of Health and Human Services payments or other transfers of value made to physicians or teaching hospitals. In February 2013, regulations were released that contain detailed guidance regarding the information that must be collected and reported. We started to be required to collect information regarding such payments in August 2013 and will be required to begin reporting such information in March 2014. Over the next several years, we will need to dedicate significant resources to enhance our systems and processes in order to comply with these regulations. The PPACA also includes various provisions designed to strengthen significantly fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Many of these requirements and standards are new and uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition.

***Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.***

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

***Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.***

As a biopharmaceutical company with significant research and development and 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, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

***Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.***

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, a number of which have yet to be fully implemented. Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

***Changes in laws and regulations affecting the healthcare industry could adversely affect our business.***

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

***Risks associated with our operations outside of the United States could adversely affect our business.***

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "*Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*");
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar and the cost of currency exchange;
- our ability to deploy overseas funds in an efficient manner;
- adverse tax consequences, including those that might result from the failure to operate in conformity with the requirements for certain tax treatment, tax incentives, or grants;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

***We face potential liability related to the privacy of health information we obtain from research institutions and our collaborators.***

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, is collaborating with the Geisinger Health System, which is subject to such regulations, and may enter into collaboration arrangements with additional institutions in the future. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA's criminal provisions could potentially be prosecuted under aiding-and-abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA's disclosure standards. In addition, international data protection laws, including the EU Data Protection Directive and member state implementing legislation, may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

**Risks Related to Our Reliance on Third Parties**

***If our antibody collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.***

We rely heavily on funding from Sanofi to support our target discovery and antibody research and development programs. Sanofi has committed to pay up to $160 million per year, or a total of $1.28 billion, between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. Sanofi also initially funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that Sanofi elects to co-develop with us. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us, such as sarilumab, alirocumab, dupilumab, enoticumab, nesvacumab, REGN1033, and REGN2009, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on Sanofi to lead the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us if they receive regulatory approval. If Sanofi does not elect to co-develop the antibodies that we discover or opts out of their development, unless we enter into a partnership agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, Sanofi has elected not to continue co-development of fasinumab, and decided not to opt in to the REGN1154, REGN 1193, REGN1500, and other programs. If Sanofi terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. Even though none of the antibodies from this collaboration may ever be successfully developed and commercialized, if Sanofi does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

***If our collaboration with Sanofi for ZALTRAP is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop and commercialize ZALTRAP, would be materially harmed.***

We rely heavily on Sanofi to lead much of the development of ZALTRAP and the commercialization of ZALTRAP. If Sanofi fails to perform its obligations in a timely manner, or at all, our ability to develop and commercialize ZALTRAP in previously-treated mCRC will be significantly adversely affected. Sanofi has the right to terminate its collaboration agreement with us at any time upon twelve months' advance notice. If Sanofi were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our collaborator, which we would have to develop or outsource at substantial additional costs to us. In particular, we have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Termination of the Sanofi collaboration agreement for ZALTRAP would create substantial new and additional risks to the successful development and commercialization of ZALTRAP.

***If our collaboration with Bayer HealthCare for EYLEA is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed.***

We rely heavily on Bayer HealthCare to assist with the development, and the commercialization outside the United States, of EYLEA. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global EYLEA development program. As the EYLEA program continues, we will continue to rely on Bayer HealthCare to assist with funding the EYLEA development program, continue to lead the development of EYLEA outside the 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 EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen Pharmaceuticals Co. Ltd. pursuant to a Co-Promotion and Distribution Agreement with Bayer HealthCare's Japanese affiliate. EYLEA is currently available in the United States, EU, Japan, and certain other countries outside of the United States for treatment of wet AMD and macular edema following CRVO. We cannot assure you that additional regulatory approvals will be received for EYLEA outside the United States or that EYLEA will be successfully commercialized. If Bayer HealthCare and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA 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 or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA outside the United States and result in substantial additional costs to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA, particularly outside the United States.

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

We depend upon third-party collaborators, including Sanofi, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers, fill/finish, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of EYLEA for the treatment of wet AMD and macular edema following CRVO, ZALTRAP for the treatment of patients with mCRC, ARCALYST for the treatment of CAPS, and our late-stage product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, GLPs, or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We rely on third-party service providers to support the distribution of EYLEA in the United States and for many other related activities in connection with the commercialization of this marketed product. Despite our arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, our sales of EYLEA will suffer.

**Risk Related to Employees**

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

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; George D. Yancopoulos, M.D., Ph.D., our Chief Scientific Officer and President, Regeneron Laboratories; and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we continue to commercialize EYLEA, we are also highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

**Information Technology Risks**

***Significant disruptions of information technology systems or breaches of data security could adversely affect our business.***

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion, and computer viruses, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others.

Such disruptions and breaches of security could result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

**Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing**

***We have a history of operating losses and have only recently achieved profitability. If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.***

Beginning in the first quarter of 2012, we reported profitability; prior to that, we generally incurred net losses. If we cannot sustain profitability, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our sales of EYLEA, and our share of the profits from Bayer HealthCare's sales of EYLEA outside the United States, or from other sources, the amount, timing, nature or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

***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 expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the ongoing marketing of EYLEA and the potential commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody product candidates we are developing on our own (without Sanofi), and expenses related to the requirement, following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being developed in collaboration with Sanofi.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable

terms or at all. Our ability to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we are able to obtain it through the sale of equity securities, such sales will likely 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 be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of EYLEA, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

***Changes in foreign currency exchange rates could have a material adverse effect on our operating results.***

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, and British pound sterling. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our company.

***Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.***

As of December 31, 2013, we had $535.6 million in cash and cash equivalents and $548.3 million in marketable securities. Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds, direct obligations of the U.S. government and its agencies, and other debt securities guaranteed by the U.S. government. These investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. If our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

**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:

- fluctuations in our operating results, in particular net product sales of EYLEA and, to a lesser degree, sales of ZALTRAP;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA;
- whether our net products sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors’ product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions or decisions by government authorities or insurers affecting the coverage or reimbursement of any of our marketed products or competitors’ products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborative partners or key customers;

- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel; and
- general market conditions.

In addition, in the fourth quarter of 2012, we determined, based on our facts and circumstances, that it was more likely than not that a substantial portion of our deferred tax assets would be realized and, as a result, substantially all of our valuation allowance against deferred tax assets was released. Therefore, beginning in 2013, we began recording income tax expense, which results in a significant reduction in our net income and net income per share and may have an impact on the market price of our Common Stock.

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. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

***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, 2013, our four largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 42.9% 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, 2013. As of December 31, 2013, Sanofi beneficially owned 15,816,953 shares of our Common Stock, representing approximately 16.2% of the shares of Common Stock then outstanding. Under our 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time may not be sold until the later of (i) December 20, 2020 and (ii) the expiration of our discovery and preclinical development agreement with Sanofi relating to our antibody collaboration (as amended) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In February 2013, we received from Sanofi a notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 that it intends to acquire additional Common Stock through open market purchases and direct purchases from shareholders. If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

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, 2013, holders of Class A Stock held 17.1% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of December 31, 2013:

- our current executive officers and directors beneficially owned 10.8% 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, 2013, and 22.9% 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, 2013; and
- our four largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 42.9% 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, 2013. In addition, these four shareholders plus our Chief Executive Officer held approximately 49.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2013.

Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our company, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

In addition, upon Sanofi reaching 20% ownership of our then outstanding shares of Class A Stock and Common Stock (taken together), we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition of 20% of our then outstanding shares of Class A Stock and Common Stock (taken together) and (ii) 25% of our then outstanding shares of Class A Stock and Common Stock (taken together). This designee is required to be “independent” of our company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi.

***The convertible note hedges and warrant transactions we entered into in connection with our convertible senior notes issuance may affect the trading price of our Common Stock.***

In connection with our offering of our 1.875% Convertible Senior Notes due October 1, 2016 ("convertible senior notes" or "notes"), we entered into convertible note hedge transactions with four financial institutions (the "hedge counterparties"), the purpose of which was to reduce the potential dilution to our Common Stock and/or offset potential cash payments in excess of the principal amount of the notes (as applicable) upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments (as applicable) as required under the convertible note hedge documents, we would not receive the benefit of such transactions. Separately, we also entered into warrant transactions with the hedge counterparties. The warrant transactions could separately have a dilutive effect from the issuance of Common Stock pursuant to the warrants.

In connection with hedging these transactions, the hedge counterparties and/or their affiliates may enter into various derivative transactions with respect to our Common Stock, and may enter into, or may unwind, various derivative transactions and/or purchase or sell our Common Stock or other securities of ours in secondary market transactions prior to maturity of the notes (and are likely to do so during any conversion period related to any conversion of the notes). These activities could have the effect of increasing or preventing a decline in, or could have a negative effect on, the value of our Common Stock and could have the effect of increasing or preventing a decline in the value of our Common Stock during any cash settlement averaging period related to a conversion of the notes.

In addition, we intend to exercise options under the convertible note hedge transactions whenever notes are converted. In order to unwind their hedge position with respect to the options we exercise, the hedge counterparties and/or their affiliates may sell shares of our Common Stock or other securities in secondary market transactions or unwind various derivative transactions with respect to our Common Stock during the cash settlement averaging period for the converted notes. The effect, if any, of any of these transactions and activities on the trading price of our Common Stock or the notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our Common Stock and the value of the notes. The derivative transactions that the hedge counterparties and/or their affiliates expect to enter into to hedge these transactions may include cash-settled equity swaps referenced to our Common Stock. In certain circumstances, the hedge counterparties and/or their affiliates may have derivative positions that, when combined with the hedge counterparties' and their affiliates' ownership of our Common Stock, if any, would give them economic exposure to the return on a significant number of shares of our Common Stock.

***The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements and our convertible senior notes and related warrant and hedge transactions, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.***

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

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder", a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned *"Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management."*

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our license and collaboration agreement with Sanofi relating to our antibody collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party's having more than 10% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our company.

Similarly, under our 2014 PDGFR-beta license and collaboration agreement with Bayer HealthCare, Bayer HealthCare is prohibited from seeking to influence the control of our company or acquiring more than 20% of our then outstanding Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our company; (iii) the acquisition (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our then outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer Healthcare; (v) other specified events, such as a liquidation or dissolution of our company.

The holders of our convertible senior notes have fundamental change purchase rights, which require us to purchase all or a portion of their notes upon the occurrence of a fundamental change, as defined in the indenture governing the notes. In addition, the indenture contains provisions requiring an increase to the conversion rate for conversions in connection with make-whole fundamental changes. These rights and provisions may in certain circumstances delay or prevent a takeover of us and the removal of incumbent management that might otherwise be beneficial to investors. In addition, upon the occurrence of certain extraordinary events, the hedge transactions would be exercised upon the conversion of notes, and the warrant transactions may be terminated. It is possible that the proceeds we receive upon the exercise of the convertible note hedge transactions would be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. Such differences may result in the acquisition of us being on terms less favorable to our shareholders than it would otherwise be.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer provide for severance benefits in the event of termination as a result of a change in control of our company. Also, many of our stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, as amended and restated, may become fully vested in connection with a “change in control” of our company, as defined in the plan. Further, under the amended and restated investor agreement between us and Sanofi, we are required under certain circumstances to appoint an individual agreed upon by us and Sanofi to our board of directors, as described above under "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management*." These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

## 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 lease in Tarrytown, New York, as amended, we lease approximately 664,000 square feet of laboratory and office facilities. In April 2013, we executed an agreement related to approximately 360,000 square feet of space that we currently lease at our Tarrytown location, which extended the term of the lease from June 2024 to June 2029; the remaining space will expire in June 2024. The lease contains three renewal options to extend the term of the lease by five years each, as well as early termination options on approximately 271,000 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses.

In April 2013, we entered into a new lease agreement for approximately 297,000 square feet of additional new laboratory and office space to be constructed in two new buildings, which are expected to be completed in the second half of 2015, at our current Tarrytown, New York location. The initial term of the lease, which is expected to commence in mid-2014, is approximately 15 years and contains three renewal options to extend the term of the lease by five years each. The lease provides for (i) monthly payments over its term, which will be based on the landlord's costs of construction and tenant allowances, and (ii) additional charges for utilities, taxes, and operating expenses.

The following table summarizes information regarding our current real property leases:

| Location | Square Footage | Expiration | Current Monthly Base Rental Charges[1] | Renewal Option Available |
|---|---|---|---|---|
| Tarrytown, New York | 664,000 | June 2024 - June 2029 | $ 2,239,000 | Three 5-year terms |
| Tarrytown, New York[2] | 297,000 | June 2029 | — | Three 5-year terms |

[1] Excludes additional charges for utilities, real estate taxes, and operating expenses, as defined.
[2] As noted above, pursuant to a new lease agreement entered into in April 2013, there are two new buildings currently under construction. Rent payments on these buildings are expected to commence in 2015.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 425,000 square feet of research, manufacturing, office, and warehouse space. In addition, we are constructing approximately 65,000 square feet of additional manufacturing space at our Rensselaer site.

In July 2013, we reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick. We intend to renovate this facility to accommodate and support our growth, primarily in connection with expanding our bulk manufacturing capacity to support our global supply chain.

In the future, we may lease, operate, purchase, or construct additional facilities in which to conduct expanded research and development and manufacturing activities and support 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.

***Proceedings Relating to '287 Patent***

As described more specifically below, we are parties to patent infringement litigation involving our European Patent No. 1,360,287 (the "'287 Patent"), which concerns genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (referred to below as "'287 Patent Infringement Litigation"), we claim infringement of several claims of the '287 Patent, and seek, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent.

On September 25, 2013, we commenced '287 Patent Infringement Litigation against Kymab Ltd, a company based in the United Kingdom, in the English High Court of Justice, Chancery Division, Patents Court, in London. On December 18, 2013, Kymab filed a defense to our lawsuit and counterclaimed alleging invalidity of the '287 Patent. Kymab previously filed an opposition to the '287 Patent in the European Patent Office in June 2013.

On January 3, 2014, we commenced '287 Patent Infringement Litigation against Novo Nordisk A/S, a company based in Denmark, in the English High Court of Justice, Chancery Division, Patents Court, in London.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

***Market for Registrant's Common Equity***

Our Common Stock, par value $.001 per share, 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 our Common Stock as reported by The NASDAQ Global Select Market:

| | High | Low |
|---|---|---|
| **2012** | | |
| First Quarter | $ 121.39 | $ 56.01 |
| Second Quarter | 145.04 | 107.31 |
| Third Quarter | 153.98 | 111.50 |
| Fourth Quarter | 188.95 | 136.13 |
| | | |
| **2013** | | |
| First Quarter | $ 185.78 | $ 154.16 |
| Second Quarter | 283.99 | 177.12 |
| Third Quarter | 319.83 | 225.78 |
| Fourth Quarter | 319.50 | 257.69 |

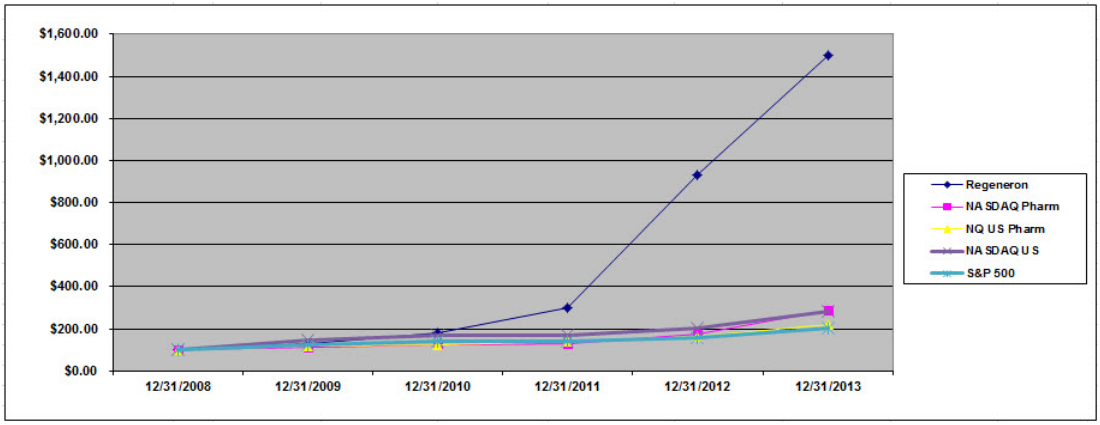
As of February 6, 2014, there were 282 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

We have never paid cash dividends on our Common Stock or Class A Stock and do not anticipate paying any in the foreseeable future.

Refer to information in Note 15. "Long-Term Incentive Plans" and Note 16. "Executive Stock Purchase Plan" under "Notes to Consolidated Financial Statements" for information related to our equity compensation plans.

## 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, (ii) The NQ US Benchmark Pharma TR Index, (iii) The NASDAQ Stock Market (U.S.) Index, and (iv) Standard & Poor's 500 Stock Index (S&P 500) for the period from December 31, 2008 through December 31, 2013. Due to the fact that total shareholder return data for the NASDAQ Pharmaceutical Stock Index will no longer be available for periods starting on or after January 1, 2014, we have included in our performance graph below the NQ US Benchmark Pharma TR Index, which we believe is a comparable index and which we plan to include in our future performance graphs. Additionally, effective May 1, 2013, we joined the S&P 500. In accordance with applicable SEC rules, the S&P 500 index information is set forth in the performance graph below. In our future performance graphs, the S&P 500 index will replace The NASDAQ Stock Market (U.S.) Index. The comparison assumes that $100 was invested on December 31, 2008 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.




| | 12/31/2008 | 12/31/2009 | 12/31/2010 | 12/31/2011 | 12/31/2012 | 12/31/2013 |
|---|---|---|---|---|---|---|
| Regeneron | $ 100.00 | $ 131.70 | $ 178.81 | $ 301.91 | $ 931.75 | $ 1,499.13 |
| NASDAQ Pharm | 100.00 | 112.36 | 121.80 | 130.38 | 173.45 | 285.96 |
| NQ US Pharm | 100.00 | 118.85 | 121.94 | 143.27 | 163.78 | 222.22 |
| NASDAQ US | 100.00 | 143.74 | 170.23 | 171.13 | 202.46 | 281.91 |
| S&P 500 | 100.00 | 123.45 | 139.23 | 139.23 | 157.90 | 204.63 |

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing of ours under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as shall be expressly set forth by specific reference to such filing.

***Issuer Purchases of Equity Securities***

The following table reflects shares of Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under our Amended and Restated Long-Term Incentive Plan.

| Period | Total Number of Shares (or Units) Purchased | Average Price Paid per Share (or Unit) | Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| 12/1/2013-12/31/2013 | 57,433 | $ 272.73 | — | — |

***Recent Sales of Unregistered Securities***

There were no unregistered sales of equity securities in 2013.

**Item 6. Selected Financial Data**

The selected financial data set forth below for the years ended December 31, 2013, 2012, and 2011 and at December 31, 2013 and 2012 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, 2010 and 2009 and as of December 31, 2011, 2010, and 2009 are derived from our audited financial statements not included in this report.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2013 | 2012 | 2011 | 2010 | 2009 |
| | (In thousands, except per share data) | | | | |
| **Statement of Operations Data** | | | | | |
| Revenues: | | | | | |
| Net product sales | $ 1,425,839 | $ 858,093 | $ 44,686 | $ 25,254 | $ 18,364 |
| Collaboration revenue | 650,400 | 493,913 | 369,681 | 386,725 | 314,457 |
| Technology licensing and other revenue | 28,506 | 26,471 | 31,457 | 47,095 | 46,447 |
| | 2,104,745 | 1,378,477 | 445,824 | 459,074 | 379,268 |
| Expenses: | | | | | |
| Research and development | 859,947 | 625,554 | 529,506 | 489,252 | 398,762 |
| Selling, general, and administrative | 329,415 | 210,755 | 117,261 | 65,201 | 52,923 |
| Cost of goods sold | 118,048 | 83,927 | 4,216 | 2,093 | 1,686 |
| Cost of collaboration manufacturing | 37,307 | 528 | — | — | — |
| | 1,344,717 | 920,764 | 650,983 | 556,546 | 453,371 |
| Income (loss) from operations | 760,028 | 457,713 | (205,159) | (97,472) | (74,103) |
| Other income (expense) | (46,668) | (43,292) | (17,733) | (6,996) | 2,151 |
| Income (loss) before income taxes | 713,360 | 414,421 | (222,892) | (104,468) | (71,952) |
| Income tax (expense) benefit [1] | (288,998) | 335,848 | 1,132 | — | 4,122 |
| Net income (loss) | $ 424,362 | $ 750,269 | $ (221,760) | $ (104,468) | $ (67,830) |
| Net income (loss) per share - basic | $ 4.33 | $ 7.92 | $ (2.45) | $ (1.26) | $ (0.85) |
| Net income (loss) per share - diluted | $ 3.81 | $ 6.75 | $ (2.45) | $ (1.26) | $ (0.85) |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2013 | 2012 | 2011 | 2010 | 2009 |
| **Balance Sheet Data** | | | | | |
| Unrestricted and restricted cash, cash equivalents, and marketable securities (current and non-current) | $ 1,083,875 | $ 587,511 | $ 810,550 | $ 626,939 | $ 390,010 |
| Total assets | 2,951,013 | 2,080,490 | 1,323,583 | 1,089,432 | 741,202 |
| Notes payable (current and non-current) | 320,315 | 296,518 | 275,019 | — | — |
| Facility lease obligations (current and non-current) | 185,197 | 160,810 | 160,514 | 160,030 | 109,022 |
| Capital lease obligations (current and non-current) | 126 | 1,309 | 2,506 | 2,829 | — |
| Stockholders' equity | 1,952,076 | 1,245,385 | 485,732 | 527,815 | 396,762 |

[1] Income tax benefit for the year ended December 31, 2012 was primarily attributable to the release of substantially all of the valuation allowance against our deferred tax assets, as described below under Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations."

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this report.*

### Overview

We are a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Our total revenues were $2,104.7 million in 2013, compared to $1,378.5 million in 2012 and $445.8 million in 2011. Our net income was $424.4 million, or $3.81 per diluted share, in 2013, compared to net income of $750.3 million, or $6.75 per diluted share, in 2012, and a net loss of $221.8 million, or $2.45 per share (basic and diluted), in 2011. Net income in 2012 included an income tax benefit of $335.8 million, primarily attributable to the release of substantially all of the valuation allowance against our deferred tax assets. Refer to "Results of Operations" below for further details of our financial results.

We currently have three marketed products:

- EYLEA (aflibercept) Injection, which is available in the United States, EU, Japan, and certain other countries outside the United States for the treatment of wet AMD and macular edema following CRVO. Net product sales of EYLEA in the United States were $1,408.7 million in 2013, $837.9 million in 2012, and $24.8 million in 2011. Bayer HealthCare records revenue from sales of EYLEA outside the United States. EYLEA net product sales outside of the United States commenced in the fourth quarter of 2012, and were $472.1 million in 2013 and $19.0 million in 2012.

  We commenced sales of EYLEA for the treatment of wet AMD in November 2011 and for the treatment of macular edema following CRVO in September 2012, following receipt of regulatory approval in the United States. Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals outside the United States, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD and macular edema secondary to CRVO pending in other countries.

  We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally the profits and losses from sales of EYLEA. In Japan, we are entitled to receive a percentage of the sales of EYLEA, as described below. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from any such sales.

- ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, which is available in the United States, EU, and certain other countries for treatment, in combination with FOLFIRI, of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen. Regulatory applications for marketing authorization of ZALTRAP for the treatment of previously treated mCRC patients in other countries have also been submitted and are currently under review by the respective regulatory agencies.

  We and Sanofi globally collaborate on the development and commercialization of ZALTRAP, and share profits and losses from commercialization of ZALTRAP, except for Japan, where we are entitled to receive a percentage of the sales of ZALTRAP, as described below. ZALTRAP net product sales, which are recorded by Sanofi, commenced in the United States in August 2012 and in Europe in the first quarter of 2013, and were $70.2 million in 2013 and $31.7 million in 2012.

- ARCALYST (rilonacept) Injection for Subcutaneous Use, which is available in the United States for the treatment of CAPS, including FCAS and MWS, in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Net product sales of ARCALYST totaled $17.1 million in 2013, $20.2 million in 2012, and $19.9 million in 2011. We do not expect future net product sales of ARCALYST for the treatment of CAPS to be significant.

Developing and commercializing new medicines entails significant risk and expense. Before significant revenues from the commercialization of our antibody candidates or new indications for our marketed products 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.

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, will expand and require additional resources. Our operating results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, and the continuation of our collaborations with Sanofi and Bayer HealthCare, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators. We cannot predict whether or when new products or new indications for our marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

We have 16 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based clinical programs are:

- EYLEA, which is in clinical trials for the treatment of DME and macular edema following BRVO in collaboration with Bayer HealthCare; and
- ZALTRAP, which is being studied in combination with our angiopoietin-2 inhibitor (nesvacumab) in oncology in collaboration with Sanofi.

Our antibody-based clinical programs include 14 fully human monoclonal antibody product candidates. The following seven are being developed in collaboration with Sanofi:

- Sarilumab (REGN88), an antibody to IL-6R, which is being developed in rheumatoid arthritis and non-infectious uveitis;
- Alirocumab (REGN727), an antibody to PCSK9, which is being developed for LDL cholesterol reduction;
- Dupilumab (REGN668), an antibody to IL-4R, which is being developed in atopic dermatitis, asthma, and nasal polyposis;
- Enoticumab (REGN421), an antibody to Dll4, a novel angiogenesis target, which is being developed in oncology;
- Nesvacumab (REGN910), an antibody to Ang2, another novel angiogenesis target, which is being developed in oncology;
- REGN1033, an antibody to GDF8, which is being developed in skeletal muscle disorders; and
- REGN2009, an antibody in clinical development against an undisclosed target.

We are developing the following six antibody product candidates independently:

- REGN1400, an antibody to ErbB3, which is being developed in oncology;
- REGN1154, an antibody in clinical development against an undisclosed target;
- REGN1500, an antibody in clinical development against an undisclosed target;
- REGN1193, an antibody in clinical development against an undisclosed target;
- REGN1908-1909, an antibody combination in clinical development against an undisclosed target; and
- Fasinumab (REGN475), an antibody to NGF, which is being developed for the treatment of pain and is currently on clinical hold by the FDA.

In addition, REGN2176-3, a combination product that is comprised of an antibody to PDGFR-beta co-formulated with EYLEA for use in ophthalmology, entered clinical development in the first quarter of 2014, and is being developed in collaboration with Bayer HealthCare.

Development of REGN846, which completed a Phase 1 study against an undisclosed target, was discontinued in the second quarter of 2013.

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 2013 and 2014 to date were, and plans for the remainder of 2014 are, as follows:

***Trap-based Clinical Programs:***

| 2013 and 2014 Events to Date | 2014 Plans |
|---|---|
| ***EYLEA*** | |
| Ÿ Bayer HealthCare received regulatory approval for EYLEA in certain European and other countries for the treatment of patients with wet AMD and continued to pursue regulatory applications for marketing approval in additional countries | Ÿ Regulatory agency decisions on additional applications outside the United States for the treatment of wet AMD and macular edema secondary to CRVO<br>Ÿ Bayer HealthCare to file for China regulatory approval for the treatment of wet AMD |
| Ÿ Bayer HealthCare received regulatory approval for EYLEA in the EU, Japan, and other certain other countries for the treatment of patients with macular edema secondary to CRVO and continued to pursue regulatory applications for marketing approval in additional countries | Ÿ Bayer HealthCare to file for additional ex-US regulatory approvals in DME and additional Asia regulatory approvals in myopic CNV<br>Ÿ Regulatory agency decisions on applications in the United States and outside the United States for the treatment of DME |
| Ÿ Initiated Phase 3 VIVID EAST-DME study in Russia, China, and other Asian countries | Ÿ Report two year results from Phase 3 VIVID-DME study and one-year results from Phase 3 macular edema following BRVO study |
| Ÿ Reported positive one year results from the Phase 3 VIVID-DME and VISTA-DME studies | Ÿ File for regulatory approvals in the United States and outside the United States for the treatment of macular edema following BRVO |
| Ÿ Submitted supplemental BLA for regulatory approval in the United States for the treatment of DME | |
| Ÿ Bayer HealthCare filed for marketing approval in the EU for the treatment of DME | |
| Ÿ Reported positive results from the Phase 3 MYRROR study in myopic CNV | |
| Ÿ Bayer HealthCare submitted the first application for regulatory approval for myopic CNV in Japan | |
| Ÿ Reported positive six month primary endpoint results for VIBRANT study in macular edema following BRVO | |
| Ÿ Bayer HealthCare opted-in to the global development and commercialization outside the United States for the treatment of macular edema following BRVO | |
| Ÿ Reported positive two year results from the Phase 3 VISTA-DME study | |
| ***ZALTRAP*** | |
| Ÿ European Commission granted marketing authorization in the European Union for ZALTRAP for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen | Ÿ Regulatory agency decisions outside the United States on additional applications for ZALTRAP in the treatment of previously treated mCRC patients |

***Antibody-based Clinical Programs:***

| | 2013 and 2014 Events to Date | 2014 Plans |
|---|---|---|
| ***Sarilumab (IL-6R Antibody)*** | Ÿ Initiated SARIL-RA-ASCERTAIN and SARIL-RA-COMPARE Phase 3 studies in rheumatoid arthritis<br>Ÿ Reported positive results from SARIL-RA-MOBILITY study<br>Ÿ Initiated SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis | Ÿ Continue enrollment in Phase 3 SARIL-RA program<br>Ÿ Continue patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis<br>Ÿ Initiate additional clinical studies |
| ***Alirocumab (PCSK9 Antibody)*** | Ÿ Completed patient enrollment in majority of Phase 3 ODYSSEY trials<br>Ÿ Reported positive results from Phase 3 ODYSSEY MONO trial<br>Ÿ Initiated Phase 3 ODYSSEY CHOICE I and ODYSSEY CHOICE II trials | Ÿ Continue enrollment of Phase 3 ODYSSEY OUTCOMES and ODYSSEY CHOICE I and II trials<br>Ÿ Report results from additional Phase 3 ODYSSEY trials |
| ***Dupilumab (IL-4R Antibody)*** | Ÿ Reported results for Phase 1b studies in atopic dermatitis<br>Ÿ Reported results from Phase 2a study in asthma. Results were also published online in the *New England Journal of Medicine*.<br>Ÿ Reported results from Phase 2 study in atopic dermatitis<br>Ÿ Initiated Phase 2b trials in atopic dermatitis and asthma<br>Ÿ Initiated Phase 2 trial in nasal polyposis | Ÿ Continue patient enrollment in Phase 2 trials<br>Ÿ Report results from Phase 2a and Phase 2b studies in atopic dermatitis<br>Ÿ Initiate Phase 3 studies |
| ***Enoticumab (Dll4 Antibody)*** | Ÿ Continued patient enrollment in Phase 1 program | Ÿ Complete patient enrollment in the expansion of the Phase 1 program |
| ***Nesvacumab (Ang2 Antibody)*** | Ÿ Continued patient enrollment in Phase 1 program | Ÿ Complete patient enrollment in the Phase 1b program in advanced malignancies<br>Ÿ Initiate clinical development in ophthalmology |
| ***REGN1033 (GDF8 Antibody)*** | Ÿ Continued patient enrollment in Phase 1 program<br>Ÿ Initiated Phase 2a study | Ÿ Complete patient enrollment in Phase 1 and Phase 2a programs |
| ***REGN2009 (target not disclosed)*** | Ÿ Initiated Phase 1 program | Ÿ Continue patient enrollment in Phase 1 program |
| ***REGN1400 (ErbB3 Antibody)*** | Ÿ Continued patient enrollment in Phase 1 program | Ÿ Continue patient enrollment in Phase 1 program |
| ***REGN1154 (target not disclosed)*** | Ÿ Completion of Phase 1 program | |
| ***REGN1500 (target not disclosed)*** | Ÿ Continued patient enrollment in Phase 1 program | Ÿ Continue patient enrollment in Phase 1 program |
| ***REGN1193 (target not disclosed)*** | Ÿ Initiated Phase 1 program | Ÿ Continue patient enrollment in Phase 1 program |
| ***REGN1908-1909 (target not disclosed)*** | Ÿ Initiated Phase 1 program | Ÿ Continue patient enrollment in Phase 1 program |
| ***REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA)*** | Ÿ Initiated Phase 1 program | Ÿ Continue patient enrollment in Phase 1 program |
| ***Fasinumab (NGF Antibody)*** | Ÿ On clinical hold | Ÿ Determine future development plan |

**Critical Accounting Policies and Use of Estimates**

A summary of the significant accounting policies that impact us is provided in Note 2 to our Consolidated Financial Statements. 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 consolidated financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our consolidated 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 consolidated financial statements are described below.

***Revenue Recognition***

*Product Revenue*

Product sales consist of U.S. sales of EYLEA and ARCALYST. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, we have no further performance obligations, and returns can be reasonably estimated. We record revenue from product sales upon delivery to our distributors and specialty pharmacies (collectively, our customers).

We sell EYLEA in the United States to three distributors and several specialty pharmacies. We sell ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers, whereas for ARCALYST, the specialty pharmacies sell the product directly to patients. For the years ended December 31, 2013, 2012, and 2011, we recorded 76%, 78%, and 42%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, product returns, and other sales-related deductions. Calculating these provisions involves estimates and judgments. We review our estimates of rebates, chargebacks, and other applicable provisions each period and record any necessary adjustments in the current period's net product sales.

The following table summarizes the provisions, and credits/payments, for these sales-related deductions; such amounts were not significant during the year ended December 31, 2011.

| ***(In millions)*** | **Rebates & Chargebacks** | **Distribution-Related Fees** | **Other Sales-Related Deductions** | **Total** |
|---|---|---|---|---|
| Balance as of December 31, 2011 | $ 0.6 | $ 1.5 | $ 0.2 | $ 2.3 |
| Provision related to current period sales | 14.2 | 45.0 | 3.0 | 62.2 |
| Credits/payments | (11.8) | (31.2) | (2.7) | (45.7) |
| Balance as of December 31, 2012 | 3.0 | 15.3 | 0.5 | 18.8 |
| Provision related to current period sales | 25.9 | 63.0 | 1.0 | 89.9 |
| Credits/payments | (24.5) | (58.6) | (1.0) | (84.1) |
| Balance as of December 31, 2013 | $ 4.4 | $ 19.7 | $ 0.5 | $ 24.6 |

*Government Rebates and Chargebacks:* We estimate reductions to product sales for Medicaid and Veterans' Administration (VA) programs, and for certain other qualifying federal and state government programs. Based upon our contracts with government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, and estimated payer mix, we estimate and record an allowance for rebates and chargebacks. Our liability for Medicaid rebates consists of estimates for claims that a state will make for a current quarter, claims for prior quarters that have been estimated for which an invoice has not

been received, and invoices received for claims from prior quarters that have not been paid. Our reserves related to discounted pricing offered to VA, Public Health Services (PHS), and other institutions (collectively, qualified healthcare providers) represent our estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices we charge to our customers. Our customers charge us for the difference between what they pay for the products and the ultimate selling price to the qualified healthcare providers. Our reserve for this discounted pricing is based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

*Distribution-Related Fees:* We have written contracts with our customers that include terms for distribution-related fees. We estimate and record distribution and related fees due to our customers based on gross sales.

*Prompt Pay Discounts:* No prompt pay discounts are currently offered to our customers on sales of EYLEA. In connection with sales of ARCALYST, we offer discounts to our customers for prompt payments. We estimate these discounts based on customer terms and historical experience, and expect that our customers will always take advantage of this discount. Therefore, we accrue 100% of the prompt pay discount that is based on the gross amount of each ARCALYST invoice at the time of sale.

*Product Returns:* Consistent with industry practice, we offer our customers a limited right to return product purchased directly from us, which is principally based upon the product's expiration date. We will accept returns for three months prior to and up to six months after the product expiration date. Product returned is generally not resalable given the nature of our products and method of administration. We develop estimates for product returns based upon historical experience, inventory levels in the distribution channel, shelf life of the product, and other relevant factors. We monitor product supply levels in the distribution channel, as well as sales by our customers of EYLEA to healthcare providers and ARCALYST to patients using product-specific data provided by our customers. If necessary, our estimates of product returns may be adjusted in the future based on actual returns experience, known or expected changes in the marketplace, or other factors.

*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 significant collaboration agreements with Sanofi and Bayer HealthCare. The terms of these collaboration agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, payments for development activities, and sharing of profits or losses arising from the commercialization of products. 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. Although we did not enter into, or materially modify, any collaboration arrangements with multiple-deliverables during the years ended December 31, 2013, 2012, and 2011, any future arrangements with multiple deliverables will be divided into separate units of accounting if the deliverables in the arrangement meet certain criteria, including whether the delivered item or items has value to the collaborator on a standalone basis. 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 receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the enhancement in value to the related development product candidate, (ii) our performance and the relative level of effort required to achieve the milestone, (iii) whether the milestone relates solely to past performance, and (iv) whether the milestone payment is considered reasonable relative to all of the deliverables and payment terms. Payments for achieving milestones which are not considered substantive are deferred 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, or we may be reimbursed for all or a significant portion of the costs of our research and development activities. 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.

Under our collaboration agreements, we share in any profits or losses arising from the commercialization of products. Our collaborator provides us with our estimated share of the profits or losses, based on net product sales less cost of goods sold and shared commercialization and other expenses, from commercialization of such products for the most recent fiscal quarter. Our share of the profit or loss is recorded as collaboration revenue. Our collaborators' estimates of net products sales and related

expenses for such quarter are reconciled to their actual net product sales and related expenses in the subsequent fiscal quarter, and our share of the profit or loss is adjusted accordingly, as necessary.

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. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize as revenue any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

***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 CROs, 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/or the period over which clinical investigators or CROs 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 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.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue expenses 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, 2013, 2012, or 2011.

***Stock-based Compensation***

We recognize stock-based compensation expense for grants of stock option awards and restricted stock under our long-term incentive plans to employees and non-employee members of our 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.

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.

***Income Taxes***

We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities 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 it is more likely than not that some portion or all of the deferred tax assets will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on various factors including our historical earnings experience by taxing jurisdiction, and forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our income tax provision in the period of such reversal. Prior to 2012, we recorded a valuation allowance that fully offset our net deferred tax assets. In the fourth quarter of 2012, based on our evaluation of various factors, including our achievement of a cumulative three-year income position as of December 31, 2012, we released substantially all of our valuation allowance against our deferred tax assets and recorded a corresponding income tax benefit as described in "Results of Operations" below. We continue to maintain a valuation allowance against certain deferred tax assets.

Uncertain tax positions are accounted for in accordance with FASB authoritative guidance, which 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.

***Inventories***

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of inventory using the first-in, first-out, or FIFO, method. We capitalize inventory costs associated with our products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. We periodically analyze our inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and write-down such inventories as appropriate. In addition, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to cost of goods sold to write down such unmarketable inventory to its estimated realizable value. In 2013, 2012, and 2011, cost of goods sold included inventory write-downs and reserves totaling $9.1 million, $17.0 million, and $0.5 million, respectively.

## Results of Operations

***Years Ended December 31, 2013 and 2012***

***Net Income***

Net income in 2013 and 2012 consists of the following:

| *(In millions)* | 2013 | 2012 |
|---|---|---|
| Revenues | $ 2,104.7 | $ 1,378.5 |
| Operating expenses | (1,344.7) | (920.8) |
| Other expenses | (46.6) | (43.3) |
| Income before income taxes | 713.4 | 414.4 |
| Income tax (expense) benefit | (289.0) | 335.8 |
| Net income | $ 424.4 | $ 750.2 |

The increase in pre-tax income is related primarily to higher net product sales of EYLEA in the United States and higher Bayer HealthCare collaboration revenue in connection with sales of EYLEA outside the United States, partly offset by higher operating expenses. However, the increase in pre-tax income was more than offset by substantially higher income tax expense in 2013 than in 2012. In 2012, we recorded a tax benefit of $335.8 million primarily related to the release of substantially all of the valuation allowance associated with our deferred tax assets. Consequently, in 2013, we began recording income tax expense based on an estimated effective tax rate.

***Revenues***

Revenues in 2013 and 2012 consist of the following:

| *(In millions)* | 2013 | 2012 |
|---|---|---|
| Net product sales | $ 1,425.8 | $ 858.1 |
| Collaboration revenue: | | |
| Sanofi | 430.1 | 423.8 |
| Bayer HealthCare | 220.3 | 70.1 |
| Total collaboration revenue | 650.4 | 493.9 |
| Technology licensing and other revenue | 28.5 | 26.5 |
| Total revenue | $ 2,104.7 | $ 1,378.5 |

*Net Product Sales*

Net product sales consist of U.S. sales of EYLEA and ARCALYST. In November 2011, we received marketing approval from the FDA for EYLEA for the treatment of wet AMD, at which time product sales commenced. In addition, in September 2012, we received marketing approval from the FDA for EYLEA for the treatment of macular edema following CRVO. In 2013, EYLEA net product sales increased to $1,408.7 million from $837.9 million in 2012 due to higher sales volume. In 2013, ARCALYST net product sales were $17.1 million compared to $20.2 million in 2012.

*Sanofi Collaboration Revenue*

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that we incurred, our share of losses in connection with Sanofi's commercialization of ZALTRAP, recognition of a substantive milestone payment in 2012, and recognition of previously deferred revenue related to non-refundable up-front payments. In addition, Sanofi collaboration revenue in 2013 was reduced by two $10.0 million up-front payments that we made to Sanofi in connection with our acquisition from Sanofi of full exclusive rights to two families of novel antibodies, as described below.

| **Sanofi Collaboration Revenue** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2013** | **2012** |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $ (30.8) | $ (25.6) |
| Substantive milestone payment | — | 50.0 |
| Reimbursement of Regeneron research and development expenses | 5.6 | 10.6 |
| Other | 9.7 | 13.3 |
| Total ZALTRAP | (15.5) | 48.3 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | 453.5 | 365.3 |
| Up-front payments to Sanofi for acquisition of rights related to two antibodies | (20.0) | — |
| Other | 12.1 | 10.2 |
| Total Antibody | 445.6 | 375.5 |
| Total Sanofi collaboration revenue | $ 430.1 | $ 423.8 |

Sanofi commenced sales of ZALTRAP for treatment, in combination with FOLFIRI, of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in the third quarter of 2012 and in certain European and other countries in the first quarter of 2013. Regeneron's share of the loss in connection with commercialization of ZALTRAP, as shown in the table below, represents our 50% share of ZALTRAP net product sales less cost of goods sold and shared commercialization and other expenses.

| **Regeneron's share of losses in connection with commercialization of ZALTRAP** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2013** | **2012** |
| Net product sales recorded by Sanofi | $ 70.2 | $ 31.7 |
| Regeneron's share of collaboration losses | (30.8) | (25.6) |

Our share of the loss in 2013 and 2012 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales. Our share of the loss for 2013 is based on nine months of actual results and an estimate for the fourth quarter. Each quarter, Sanofi provides us with an estimate of our share of the profit or loss from commercialization of ZALTRAP for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

In 2012, we earned a $50.0 million substantive milestone payment from Sanofi upon FDA approval of ZALTRAP. Sanofi's reimbursement of our ZALTRAP research and development expenses decreased in 2013 compared to 2012, primarily due to a decrease in research and development activities and lower costs related to manufacturing ZALTRAP prior to regulatory approval. Other ZALTRAP revenue primarily consisted of recognition of deferred revenue related to the ZALTRAP up-front payments from Sanofi and reimbursement of other ZALTRAP-related expenses. The decrease in other revenue resulted primarily from lower recognition of deferred revenue in 2013, due to lengthening the estimated performance period over which this deferred revenue is being recognized, effective in the first quarter of of 2013. In connection with recognition of deferred revenue related to ZALTRAP, as of December 31, 2013, $6.0 million of the original $105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

In 2013, Sanofi's reimbursement of our antibody expenses consisted of $160.0 million under our discovery agreement and $293.5 million of development costs under our license agreement, compared to $181.9 million and $183.4 million, respectively, in 2012. Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery activities. In 2010, as we scaled up our capacity to conduct antibody discovery activities, Sanofi funded only $137.7 million of our preclinical research under the expanded collaboration and the balance between that amount and $160.0 million was added to the funding otherwise available to us in 2011-2012. As a result, Sanofi funded more of our discovery activities in 2012 than in 2013. The higher reimbursement of development costs in 2013 compared to 2012 was primarily due to increased development activities for alirocumab and dupilumab.

As described above, in May 2013, we made two $10.0 million up-front payments to Sanofi in connection with acquiring from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology.

Other antibody revenue relates primarily to recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of December 31, 2013, $60.5 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

*Bayer HealthCare Collaboration Revenue*

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of our share of profits in connection with commercialization of EYLEA outside the United States, recognition of sales and substantive development milestone payments, cost-sharing of Regeneron EYLEA development expenses, reimbursement of other Regeneron EYLEA expenses, and revenue related to a non-refundable $75.0 million up-front payment received in 2006 and a $20.0 million milestone payment received in 2007 (which, for the purpose of revenue recognition, was not considered substantive).

| **Bayer HealthCare Collaboration Revenue** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2013** | **2012** |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $ 101.5 | $ — |
| Sales and substantive development milestone payments | 70.0 | 25.0 |
| Cost-sharing of Regeneron EYLEA development expenses | 20.9 | 34.9 |
| Other | 27.9 | 10.2 |
| Total Bayer HealthCare collaboration revenue | $ 220.3 | $ 70.1 |

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in the fourth quarter of 2012 and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

| **Regeneron's Net Profit from EYLEA Sales Outside the United States** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2013** | **2012** |
| Net product sales outside the United States | $ 472.1 | $ 19.0 |
| Regeneron's share of collaboration profit from sales outside the United States | 159.1 | 4.2 |
| Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation | (57.6) | (4.2) |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $ 101.5 | $ — |

Bayer HealthCare records revenue from sales of EYLEA outside the United States. Our share of the profit for 2013 is based on nine months of actual results and an estimate for the fourth quarter. Each quarter, Bayer HealthCare provides us with an estimate

of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In 2013 and 2012, our share of the profit we earned from commercialization of EYLEA outside the United States was offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

In 2013, we earned $15.0 million and $10.0 million substantive development milestone payments from Bayer HealthCare upon receipt of marketing and pricing approval, respectively, outside the United States for EYLEA for the treatment of macular edema secondary to CRVO. In addition, we earned, and recorded as revenue in 2013, three $15.0 million sales milestone payments from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $200 million, $300 million, and $400 million, respectively, over a twelve-month period. In 2012, we earned $15.0 million and $10.0 million substantive milestone payments from Bayer HealthCare upon receipt of marketing and pricing approval, respectively, in Japan for EYLEA for the treatment of wet AMD.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in 2013 compared to 2012, as we incurred lower costs in connection with winding down various Phase 3 EYLEA clinical studies.

Other revenue principally consists of (i) reimbursement of other Regeneron EYLEA expenses, primarily related to Bayer HealthCare's share of royalties payable to Genentech in connection with sales of EYLEA outside the United States, which commenced in May 2013, and (ii) recognition of deferred revenue related to the up-front and 2007 milestone payments from Bayer HealthCare. As described further below under "*License and Settlement Agreements with Genentech*", in May 2013, we entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech to include all sales of EYLEA worldwide in our royalty obligation. As of December 31, 2013, $21.7 million of the up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

*Technology Licensing and Other Revenue*

In connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In both 2013 and 2012, we recognized $23.6 million of technology licensing and other revenue related to this agreement. As of December 31, 2013, $104.6 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

Under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' canakinumab. In 2013 and 2012, technology licensing and other revenue included $4.8 million and $2.8 million, respectively, of royalties from Novartis.

***Expenses***

Total operating expenses increased to $1,344.7 million in 2013 from $920.8 million in 2012. Our average headcount in 2013 increased to 2,153 from 1,827 in 2012, principally in connection with expanding our research and development, and commercialization activities.

Operating expenses in 2013 and 2012 included a total of $198.4 million and $94.2 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in 2013 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2012 compared to recent prior years. As of December 31, 2013, unrecognized Non-cash Compensation Expense related to outstanding (i) non-performance based stock options was $492.5 million, (ii) performance based stock options was $4.2 million, and (iii) unvested restricted stock awards was $43.7 million. We expect to recognize this Non-cash Compensation Expense over weighted-average periods of 1.8 years, 1.0 years, and 3.8 years, respectively.

*Research and Development Expenses*

Research and development expenses increased to $859.9 million in 2013 from $625.6 million in 2012. The following table summarizes the major categories of our research and development expenses in 2013 and 2012:

| **Research and Development Expenses** | **Year ended December 31,** | | **Increase** |
|---|---|---|---|
| ***(In millions)*** | **2013** | **2012** | **(Decrease)** |
| Payroll and benefits [1] | $ 294.2 | $ 212.1 | $ 82.1 |
| Clinical trial expenses | 139.5 | 92.3 | 47.2 |
| Clinical manufacturing costs [2] | 225.3 | 165.0 | 60.3 |
| Research and other development costs | 73.1 | 58.0 | 15.1 |
| Occupancy and other operating costs | 94.9 | 76.3 | 18.6 |
| Cost-sharing of Bayer HealthCare and Sanofi development expenses [3] | 32.9 | 21.9 | 11.0 |
| Total research and development expenses | $ 859.9 | $ 625.6 | $ 234.3 |

[1] Includes Non-cash Compensation Expense of $101.9 million in 2013 and $48.4 million in 2012.

[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, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes Non-cash Compensation Expense of $14.6 million and $5.4 million in 2013 and 2012, respectively.

[3] Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incur certain development expenses, we also recognize, as additional research and development expense, the portion of our collaboration partners' development expenses that we are obligated to reimburse. Our collaboration partners provide us with estimated development expenses for the most recent fiscal quarter. Bayer HealthCare and Sanofi’s estimates are reconciled to their actual expenses for such quarter in the subsequent fiscal quarter and our portion of our collaboration partners' development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to higher costs for clinical studies of alirocumab, dupilumab, and early stage antibody product candidates, partly offset by lower costs related to our Phase 3 trials of EYLEA in wet AMD and macular edema following CRVO, and ARCALYST, which have concluded. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing alirocumab, sarilumab, and dupilumab, partly offset by lower costs related to manufacturing clinical supplies of ARCALYST. Research and other development costs increased primarily due to higher costs associated with our early stage research and development programs and regulatory submissions for marketing approvals for EYLEA. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and higher information technology and facility-related costs at our Tarrytown and Rensselaer, New York sites. Cost-sharing of Bayer HealthCare and Sanofi development expenses increased primarily due to our obligation to fund 20% of Sanofi's Phase 3 alirocumab and sarilumab development costs, which commenced during the fourth quarter of 2013.

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 collaborations with Bayer HealthCare and Sanofi, the portion of Bayer HealthCare and Sanofi's development expenses which they incur, 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,** | | **Increase** |
|---|---|---|---|
| ***(In millions)*** | **2013** | **2012** | **(Decrease)** |
| EYLEA | $ 133.3 | $ 132.7 | $ 0.6 |
| Alirocumab | 152.2 | 70.1 | 82.1 |
| Sarilumab | 51.9 | 27.7 | 24.2 |
| Dupilumab | 89.0 | 34.9 | 54.1 |
| ARCALYST | 6.4 | 38.2 | (31.8) |
| Other antibody candidates in clinical development | 113.9 | 101.2 | 12.7 |
| Other research programs and unallocated costs | 313.2 | 220.8 | 92.4 |
| Total research and development expenses | $ 859.9 | $ 625.6 | $ 234.3 |

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a 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.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part I, Item 1A, “Risk Factors”. The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

*Selling, General, and Administrative Expenses*

Selling, general, and administrative expenses increased to $329.4 million in 2013 from $210.8 million in 2012 primarily due to higher expenses in connection with commercialization of EYLEA, including the Branded Prescription Drug Fee (as described in the Liquidity and Capital Resources section below) and contributions to a not-for-profit organization that assists patients with chronic disease conditions, and higher Non-cash Compensation Expense principally for the reason described under "Expenses" above. Selling, general, and administrative expenses included $80.0 million and $39.2 million of Non-cash Compensation Expense in 2013 and 2012, respectively.

*Cost of Goods Sold*

Cost of goods sold increased to $118.0 million in 2013 from $83.9 million in 2012 due primarily to increased sales of EYLEA. Cost of goods sold primarily consisted of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies. In addition, in 2013 and 2012, cost of goods sold included inventory write-downs and reserves totaling $9.1 million and $17.0 million, respectively. We record a charge to cost of goods sold to write down our inventory to its estimated realizable value if certain batches or units of product do not meet quality specifications or are expected to expire prior to sale.

*Cost of Collaboration Manufacturing*

We manufacture commercial supplies of product for our collaborators. Cost of collaboration manufacturing increased to $37.3 million in 2013 from $0.5 million in 2012 primarily due to the launch of EYLEA outside the United States in the fourth quarter of 2012. Cost of collaboration manufacturing primarily consists of third-party royalties, as well as costs in connection with producing commercial supplies for our collaborators. When the product is sold by our collaborators to third-party customers, our risk of inventory loss no longer exists, and we therefore recognize our related manufacturing costs for the sold product as cost of collaboration manufacturing.

***Other Income and Expense***

Total other expenses increased to $46.7 million in 2013 from $43.3 million in 2012. Other expenses consist of investment (expense) income and interest expense.

In 2013, we had net investment expense of $0.2 million, compared to net investment income of $2.0 million in 2012. In the fourth quarter of 2013, we recorded a $2.9 million other-than-temporary impairment of an equity security based upon the length of time that the security was in an unrealized loss position and our expectation that we will not hold the security until a potential recovery in value occurs. This impairment charge fully offset investment income earned in 2013 on our marketable securities.

Interest expense in 2013 and 2012 primarily includes interest associated with our $400.0 million aggregate principal amount of 1.875% convertible senior notes, including amortization of the note discount and debt issuance costs, and interest associated with our facility lease obligations.

***Income Taxes***

In 2013, we recorded income tax expense of $289.0 million, based on an effective tax rate of 40.5%. The difference between the U.S. federal statutory rate of 35% and our effective tax rate for 2013 is primarily due to increases related to state and local taxes, the non-deductible Branded Prescription Drug Fee, and losses incurred in foreign jurisdictions with rates lower than the federal statutory rate. These increases were partially offset by federal and state income tax credits. In January 2013, the American Taxpayer Relief Act was enacted, which included a provision to extend the income tax credit for increased research activities retroactively to the tax year ended December 31, 2012, as well as for 2013. As a result of the extension, during 2013, we recognized the benefit of both the 2012 and 2013 federal research tax credit.

In the fourth quarter of 2012, we recorded a $335.8 million income tax benefit, primarily attributable to the release of substantially all of the valuation allowance against our deferred tax assets. The decision to release this valuation allowance was made after we determined that it was more likely than not that these deferred tax assets would be realized, and was based on the evaluation and weighting of positive and negative evidence, including our achievement of a cumulative three-year income position in the fourth quarter of 2012. In addition, we considered forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Therefore, starting in 2013, we recorded income tax expense on income using an estimated effective tax rate.

We expect our effective tax rate to increase in 2014, primarily due to a shift in our geographic mix of profits and losses as we continue our international expansion. In addition, the federal income tax credit for increased research activities expired on December 31, 2013; as a result, unless tax legislation is enacted to extend or make permanent this federal income tax credit, we expect it will cause our effective tax rate to increase.

***Years Ended December 31, 2012 and 2011***

***Net Income (Loss)***

We reported net income of $750.3 million, or $7.92 per basic share and $6.75 per diluted share, for the year ended December 31, 2012, compared to a net loss of $221.8 million, or $2.45 per share (basic and diluted), for 2011. Our net income in 2012 resulted primarily from net product sales of EYLEA, which we launched in November 2011, and an income tax benefit of $335.8 million, primarily attributable to the release of substantially all of the valuation allowance against our deferred tax assets. In 2012, we also earned a $50.0 million substantive milestone payment from Sanofi upon FDA approval of ZALTRAP and $25.0 million of substantive milestone payments from Bayer HealthCare upon receipt of marketing and pricing approvals in Japan for EYLEA for the treatment of wet AMD.

***Revenues***

Revenues in 2012 and 2011 consist of the following:

| ***(In millions)*** | **2012** | **2011** |
|---|---|---|
| Net product sales | $ 858.1 | $ 44.7 |
| Collaboration revenue: | | |
| Sanofi | 423.8 | 326.6 |
| Bayer HealthCare | 70.1 | 43.1 |
| Total collaboration revenue | 493.9 | 369.7 |
| Technology licensing and other revenue | 26.5 | 31.4 |
| Total revenue | $ 1,378.5 | $ 445.8 |

*Net Product Sales*

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We record product sales net of allowances and accruals for prompt pay discounts, rebates and chargebacks under governmental programs (including Medicaid), product returns, and distribution-related fees. In November 2011, we received marketing approval from the FDA for EYLEA for the treatment of wet AMD, at which time product sales commenced. In addition, in September 2012, we received marketing approval from the FDA for EYLEA for the treatment of macular edema following CRVO. In 2012 and 2011, we recognized $837.9 million and $24.8 million, respectively, of EYLEA net product sales. In 2012 and 2011, we also recognized ARCALYST net product sales of $20.2 million and $19.9 million, respectively.

*Sanofi Collaboration Revenue*

The collaboration revenue we earned from Sanofi, as detailed below, consisted primarily of reimbursement for research and development expenses that we incurred, recognition of our share of losses in connection with Sanofi's commercialization of ZALTRAP, recognition of a substantive milestone payment, and recognition of revenue related to non-refundable up-front payments of $105.0 million related to the ZALTRAP collaboration and $85.0 million related to the antibody collaboration.

| **Sanofi Collaboration Revenue** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2012** | **2011** |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $ (25.6) | $ (9.3) |
| Substantive milestone payment | 50.0 | — |
| Reimbursement of Regeneron research and development expenses | 10.6 | 16.9 |
| Other | 13.3 | 9.9 |
| Total ZALTRAP | 48.3 | 17.5 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | 365.3 | 299.3 |
| Other | 10.2 | 9.8 |
| Total Antibody | 375.5 | 309.1 |
| Total Sanofi collaboration revenue | $ 423.8 | $ 326.6 |

In August 2012, the FDA approved ZALTRAP for treatment, in combination with FOLFIRI, of patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen. Regeneron's share of the loss in connection with commercialization of ZALTRAP, as shown in the table below, represents our 50% share of ZALTRAP net product sales less cost of goods sold and shared commercialization and other expenses. Our share of the loss increased in 2012, compared to 2011, due to an increase in commercialization activities in preparation for potential regulatory approvals. Sanofi provides us with an estimate of our share of the profit or loss from commercialization of ZALTRAP for the most recent fiscal quarter. Sanofi's estimates of net products sales and related expenses for such quarter are reconciled to their actual net product sales and related expenses in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

| **Regeneron's share of losses in connection with commercialization of ZALTRAP** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2012** | **2011** |
| Net product sales recorded by Sanofi | $ 31.7 | — |
| Regeneron's share of collaboration losses | (25.6) | $ (9.3) |

In 2012, we earned a $50.0 million substantive milestone payment from Sanofi upon FDA approval of ZALTRAP. Sanofi's reimbursement of our ZALTRAP research and development expenses decreased in 2012 compared to 2011, primarily due to a decrease in research and development activities and lower costs related to manufacturing ZALTRAP prior to regulatory approval. Other ZALTRAP revenue includes recognition of deferred revenue related to the up-front payments from Sanofi, which increased in 2012 from 2011 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the second quarter of 2012.

In 2012, Sanofi's reimbursement of our antibody expenses consisted of $181.9 million under our discovery agreement and $183.4 million of development costs under our license agreement, compared to $161.9 million and $137.4 million, respectively, in 2011. The higher reimbursement amount under the discovery agreement in 2012 compared to 2011 was primarily due to an increase in our antibody discovery activities. The higher reimbursement of development costs in 2012 compared to 2011 was primarily due to increased development activities for alirocumab.

Other antibody revenue relates primarily to recognition of deferred revenue from an $85.0 million up-front payment and other payments. As it relates to recognition of deferred revenue, in connection with the November 2009 amendment of the discovery agreement, Sanofi has funded $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to such funding from Sanofi was deferred and is being recognized as collaboration

revenue prospectively over the related performance period in conjunction with the recognition of the original $85.0 million up-front payment.

*Bayer HealthCare Collaboration Revenue*

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted primarily of cost-sharing of Regeneron EYLEA development expenses, recognition of substantive milestone payments, and recognition of revenue related to a non-refundable $75.0 million up-front payment received in 2006, and a $20.0 million milestone payment received in 2007 (which, for the purpose of revenue recognition, was not considered substantive).

| **Bayer HealthCare Collaboration Revenue** | **Year ended December 31,** | |
|---|---|---|
| ***(In millions)*** | **2012** | **2011** |
| Cost-sharing of Regeneron EYLEA development expenses | $ 34.9 | $ 33.7 |
| Substantive milestone payments | 25.0 | — |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | — | — |
| Other | 10.2 | 9.4 |
| Total Bayer HealthCare collaboration revenue | $ 70.1 | $ 43.1 |

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare increased slightly in 2012 compared to 2011. In 2012, we incurred higher costs in connection with regulatory and other development activities, partly offset by lower costs in connection with our Phase 3 VIEW 1 study in wet AMD, which has concluded. In 2012, we earned $15.0 million and $10.0 million substantive milestone payments from Bayer HealthCare upon receipt of marketing and pricing approval, respectively, in Japan for EYLEA for the treatment of wet AMD.

In the fourth quarter of 2012, Bayer HealthCare launched EYLEA for the treatment of wet AMD outside of the United States. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below. Our share of the profit we earned from commercialization of EYLEA outside the United States was fully offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

| **Regeneron's Net Profit from EYLEA Sales Outside the United States** | **Year ended** |
|---|---|
| ***(In millions)*** | **December 31, 2012** |
| Net product sales outside the United States recorded by Bayer HealthCare | $ 19.0 |
| Regeneron's share of collaboration profit from sales outside the United States | 4.2 |
| Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation | (4.2) |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $ — |

Other revenue principally consisted of recognition of deferred revenue related to the up-front and 2007 milestone payments from Bayer HealthCare.

*Technology Licensing and Other Revenue*

In connection the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In connection with our *VelocImmune* license agreement with AstraZeneca, which terminated effective as of February 2011, the $20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably through February 2011. In 2012 and 2011, we recognized $23.6 million and $24.8 million, respectively, of technology licensing and other revenue related to these agreements.

Technology licensing and other revenue in 2011 also included $3.6 million recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project. As of the end of 2011, no further revenue has been recognized by us in connection with this NIH Grant. In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' canakinumab. In 2012 and 2011, technology licensing and other revenue included $2.8 million and $2.3 million, respectively, of royalties from Novartis.

***Expenses***

Total operating expenses increased to $920.8 million in 2012 from $651.0 million in 2011. Our average headcount in 2012 increased to 1,827 from 1,568 in 2011, principally in connection with expanding our antibody research and development activities and commercialization activities, primarily for EYLEA in the United States.

Operating expenses in 2012 and 2011 included a total of $94.2 million and $56.1 million, respectively, of Non-cash Compensation Expense. The increase in total Non-cash Compensation Expense in 2012 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2011 and 2012 compared to recent prior years.

*Research and Development Expenses*

Research and development expenses increased to $625.6 million in 2012 from $529.5 million in 2011. The following table summarizes the major categories of our research and development expenses in 2012 and 2011:

| **Research and Development Expenses** | **Year ended December 31,** | | **Increase** |
|---|---|---|---|
| ***(In millions)*** | **2012** | **2011** | **(Decrease)** |
| Payroll and benefits [1] | $ 212.1 | $ 168.9 | $ 43.2 |
| Clinical trial expenses | 92.3 | 67.6 | 24.7 |
| Clinical manufacturing costs [2] | 165.0 | 123.0 | 42.0 |
| Research and other development costs | 58.0 | 60.4 | (2.4) |
| Occupancy and other operating costs | 76.3 | 61.8 | 14.5 |
| Cost-sharing of Bayer HealthCare EYLEA development expenses [3] | 21.9 | 47.8 | (25.9) |
| Total research and development expenses | $ 625.6 | $ 529.5 | $ 96.1 |

[1] Includes Non-cash Compensation Expense of $48.4 million in 2012 and $29.3 million in 2011.

[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, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes Non-cash Compensation Expense of $5.4 million and $3.5 million in 2012 and 2011, respectively.

[3] Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs EYLEA development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's EYLEA development expenses that we are obligated to reimburse.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to higher costs for clinical studies of our antibody candidates, especially alirocumab and dupilumab, and higher costs related to our Phase 3 studies of EYLEA in DME and macular edema following BRVO, partly offset by lower costs related to our Phase 3 VIEW 1 trial of EYLEA in wet AMD, which has concluded. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing alirocumab, certain other antibody

candidates, and clinical supplies of EYLEA, partly offset by lower costs related to manufacturing clinical supplies of ARCALYST. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and higher information technology and facility-related costs. Cost-sharing of Bayer HealthCare's EYLEA development expenses decreased primarily due to lower costs in connection with Bayer HealthCare's wet AMD development activities, including the VIEW 2 trial, which has concluded.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's EYLEA development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

| **Project Costs** | **Year ended December 31,** | | **Increase** |
|---|---|---|---|
| ***(In millions)*** | **2012** | **2011** | **(Decrease)** |
| EYLEA | $ 132.7 | $ 147.6 | $ (14.9) |
| ARCALYST | 38.2 | 43.2 | (5.0) |
| ZALTRAP | 13.7 | 17.1 | (3.4) |
| Alirocumab | 70.1 | 33.9 | 36.2 |
| Sarilumab | 27.7 | 27.3 | 0.4 |
| Dupilumab | 34.9 | 26.6 | 8.3 |
| Other antibody candidates in clinical development | 87.5 | 48.1 | 39.4 |
| Other research programs and unallocated costs | 220.8 | 185.7 | 35.1 |
| Total research and development expenses | $ 625.6 | $ 529.5 | $ 96.1 |

*Selling, General, and Administrative Expenses*

Selling, general, and administrative expenses increased to $210.8 million in 2012 from $117.3 million in 2011 due to higher selling expenses in connection with commercialization of EYLEA, higher headcount, and higher Non-cash Compensation Expense principally for the reason described above. Selling, general, and administrative expenses included $39.3 million and $23.3 million of Non-cash Compensation Expense in 2012 and 2011, respectively.

*Cost of Goods Sold*

Cost of goods sold increased to $83.9 million in 2012 from $4.2 million in 2011 due primarily to our launch of EYLEA in November 2011. Cost of goods sold primarily consisted of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies. In addition, in 2012 and 2011, cost of goods sold included inventory write-downs and reserves totaling $17.0 million and $0.5 million, respectively. We record a charge to cost of goods sold to write down our inventory to its estimated realizable value if certain batches or units of product do not meet quality specifications or are expected to expire prior to sale.

***Other Income and Expense***

Total other expenses increased to $43.3 million in 2012 from $17.7 million in 2012. Other expenses consist of investment income and interest expense.

Investment income decreased to $2.0 million in 2012 from $3.5 million in 2011 due primarily to lower yields on cash and marketable securities. Interest expense increased to $45.3 million in 2012 from $21.3 million in 2011. In October 2011, we issued $400.0 million aggregate principal amount of 1.875% convertible senior notes. Total interest expense in 2012 and 2011 associated with these notes, including amortization of the note discount and debt issuance costs, was $29.1 million and $5.4 million, respectively.

***Income Taxes***

In the fourth quarter of 2012, we recorded a $335.8 million income tax benefit, primarily attributable to the release of substantially all of the valuation allowance against our deferred tax assets. The decision to release this valuation allowance was made after we determined that it was more likely than not that these deferred tax assets would be realized, and was based on the evaluation and weighting of positive and negative evidence, including our achievement of a cumulative three-year income position in the fourth quarter of 2012. In addition, we considered forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration.

In 2011, we recorded a $1.1 million income tax benefit, which consisted primarily of $0.7 million related to tax legislation that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

**Liquidity and Capital Resources**

***Sources and Uses of Cash for the Years Ended December 31, 2013, 2012, and 2011***

At December 31, 2013, we had $1,083.9 million in cash, cash equivalents, and marketable securities compared with $587.5 million (including $8.2 million of restricted cash and marketable securities) at December 31, 2012 and $810.6 million (including $7.7 million of restricted cash and marketable securities) at December 31, 2011. In connection with our U.S. product launch of EYLEA in the fourth quarter of 2011, we have offered extended payment terms to our EYLEA customers. As a result, due to the growth of our EYLEA product sales, our net trade accounts receivable (none of which are past due) increased to $787.1 million at December 31, 2013 from $593.2 million at December 31, 2012 and $28.3 million at December 31, 2011. During 2013, we collected $1,302.0 million of EYLEA trade receivables. Effective January 2014, we have shortened the payments terms to certain of our EYLEA customers, which will reduce our cash collection cycle.

As described above, in 2013 we earned and received a total of $70.0 million in milestone payments from Bayer HealthCare. In 2012, we earned and received a $50.0 million milestone payment from Sanofi, and $25.0 million of milestone payments from Bayer HealthCare. We also made a $60.0 million lump-sum payment in the third quarter of 2012, under our Non-Exclusive License and Partial Settlement Agreement with Genentech, when cumulative U.S. sales of EYLEA reached $400.0 million.

In October 2011, we completed a private placement of $400.0 million aggregate principal amount of 1.875% convertible senior notes and received net proceeds of $391.1 million after deducting the initial purchaser's discount and issuance costs. In connection with the offering of the convertible senior notes, we entered into convertible note hedge and warrant transactions, which had a net cost to us of $23.7 million.

*Cash Provided by (Used in) Operating Activities*

Net cash provided by operating activities was $583.6 million in 2013. Our net income of $424.4 million in 2013 included the following non-cash expenses: (i) Non-cash Compensation Expense of $198.4 million, (ii) depreciation and amortization of $41.2 million, (iii) non-cash interest expense of $23.1 million, primarily resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011, and (iv) other non-cash charges of $23.7 million, which includes $9.1 million of inventory write-downs and reserves. In addition, deferred tax assets at December 31, 2013 decreased by $63.6 million, compared to end-of-year 2012, primarily due to utilization of net operating loss and tax credit carry-forwards to offset income taxes payable during 2013.

At December 31, 2013, Sanofi and trade accounts receivable increased by $198.7 million, compared to end-of-year 2012, primarily due to higher trade accounts receivable in connection with U.S. EYLEA product sales, as described above. Inventories increased by $48.0 million, compared to end-of-year 2012, primarily in connection with increased production of EYLEA commercial supplies. Prepaid expenses and other assets increased by $52.8 million, compared to end-of-year 2012, primarily due to an increase in our receivable balance due from Bayer HealthCare in connection with the launch of EYLEA outside the United States. Our deferred revenue at December 31, 2013 decreased by $28.0 million, compared to end-of-year 2012, primarily due to amortization of a previously received and deferred $165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations, partly offset by costs of product manufactured for Sanofi and Bayer HealthCare for which recognition of revenue has been deferred. Accounts payable, accrued expenses, and other liabilities increased by $136.7 million at December 31, 2013, compared to end-of-year 2012, primarily due to (i) higher sales-related charges, deductions, and royalties related to EYLEA, (ii) higher payroll-related liabilities, due in part to funding payment of our year-end 2012 employee cash bonuses in 2012, whereas year-end 2013 employee cash bonuses were accrued in 2013 and paid in 2014, and (iii) higher expenditures in connection with our expanding commercial and research and development activities.

Net cash used in operating activities was $74.6 million in 2012. Our net income of $750.3 million in 2012 included (i) a non-cash tax benefit of $340.2 million resulting from the release of substantially all of the valuation allowance against our deferred tax assets, as previously described above, (ii) Non-cash Compensation Expense of $94.2 million, (iii) depreciation and amortization of $36.9 million, (iv) non-cash interest expense of $22.9 million, including $21.6 million resulting from the amortization of the discount and debt issuance costs in connection with our convertible senior notes, which were issued in October 2011, and (v) other non-cash charges of $34.0 million, including inventory write-downs and reserves of $17.0 million.

At December 31, 2012, Sanofi and trade accounts receivable increased by $590.1 million, compared to end-of-year 2011, primarily due to higher trade accounts receivable in connection with EYLEA product sales, as described above. Inventories increased by $28.9 million, compared to end-of-year 2011, primarily in connection with production of EYLEA commercial supplies. Prepaid expenses and other current assets increased by $23.7 million, compared to end-of-year 2011, primarily due to an increase in prepaid royalties resulting from the $60.0 million payment we made in the third quarter of 2012, as described above. Our deferred revenue at December 31, 2012 decreased by $41.1 million, compared to end-of-year 2011, primarily due to amortization of a previously received and deferred $165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $11.0 million at December 31, 2012, compared to end-of-year 2011, primarily due to higher sales-related deductions in connection with EYLEA and higher expenditures in connection with our expanding commercial and research and development activities, partly offset by lower payroll-related liabilities due to payment of our year-end 2012 employee cash bonuses in 2012, whereas year-end 2011 employee cash bonuses were accrued in 2011 and paid in January 2012.

Net cash used in operating activities was $141.7 million in 2011. Our net loss of $221.8 million in 2011 included Non-cash Compensation Expense of $56.1 million and depreciation and amortization of $31.1 million. At December 31, 2011, Sanofi and trade accounts receivable increased by $21.1 million, compared to end-of-year 2010, primarily due to EYLEA product sales, which commenced in the fourth quarter of 2011. Due to the payment terms granted to our customers, our EYLEA product sales in 2011, generally, had not yet been collected as of December 31, 2011. Our deferred revenue at December 31, 2011 decreased by $40.3 million, compared to end-of-year 2010, primarily due to amortization of a previously received and deferred $165.0 million payment under our license agreement with Astellas and amortization of previously deferred payments under our Sanofi and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased by $50.0 million at December 31, 2011, compared to end-of-year 2010, primarily in connection with (i) higher payroll-related liabilities, due in part to funding payment of our year-end 2010 employee cash bonuses in 2010 whereas year-end 2011 employee cash bonuses were accrued in 2011 and funded in 2012 and (ii) our expanded levels of activities and expenditures, partly in connection with EYLEA commercialization activities.

*Cash (Used in) Provided by Investing Activities*

Net cash used in investing activities was $355.5 million and $81.1 million in 2013 and 2012, respectively, and net cash provided by investing activities was $128.5 million in 2011. In 2013 and 2012, purchases of marketable securities exceeded sales or maturities by $199.1 million and $31.2 million, respectively. In 2011, sales or maturities of marketable securities exceeded purchases by $186.0 million. Capital expenditures of $156.3 million, $49.3 million, and $57.2 million in 2013, 2012, and 2011, respectively, included costs in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvement and associated costs related to our leased facilities in Tarrytown, New York.

*Cash Provided by (Used in) Financing Activities*

Net cash provided by financing activities was $77.1 million and $384.2 million in 2013 and 2011, respectively, and net cash used in financing activities was $97.6 million in 2012. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $57.4 million in 2013 compared to $63.5 million in 2012 and $43.6 million in 2011. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted Common Stock were $195.1 million in 2013 compared to $163.3 million in 2012 and $25.1 million in 2011. Cash flows from financial activities also increased by $216.9 million in 2013 due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations. As described above, in October 2011, we completed a private placement of convertible senior notes and entered into convertible note hedge and warrant transactions.

***Fair Value of Marketable Securities***

At December 31, 2013 and 2012, we held $548.3 million and $354.9 million, respectively, of marketable securities which consisted of debt securities issued by investment grade institutions as well as equity securities. The composition of our portfolio of marketable securities on these dates was as follows:

| | December 31, 2013 | | December 31, 2012 | |
|---|---|---|---|---|
| **Investment type** | **Fair Value** | **Percent** | **Fair Value** | **Percent** |
| *Unrestricted* | | | | |
| U.S. government and government agency obligations | $ 107.5 | 20% | $ 328.1 | 92% |
| Corporate bonds | 369.2 | 68% | — | — |
| Commercial paper | 24.0 | 4% | — | — |
| Municipal bonds | 36.9 | 7% | 17.5 | 5% |
| International government agency obligations | 2.0 | — | — | — |
| Certificates of deposit | 7.5 | 1% | — | — |
| Equity securities | 1.2 | — | 3.4 | 1% |
| Total unrestricted marketable securities | 548.3 | 100% | 349.0 | 98% |
| *Restricted* | | | | |
| U.S. government obligations | — | — | 5.9 | 2% |
| Total marketable securities | $ 548.3 | 100% | $ 354.9 | 100% |

In addition, at December 31, 2013, we had $535.6 million of cash and cash equivalents, primarily held in bank deposits and money market funds. At December 31, 2012, we had $232.6 million of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities. During 2013, due to cancellation of lender collateralization requirements, all formerly restricted marketable securities were reclassified as unrestricted on our balance sheet.

Our methods for valuing our marketable securities are described in Note 7 to our Consolidated Financial Statements.

***Collaborations with Sanofi***

*ZALTRAP (aflibercept)*

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to Sanofi U.S.) to collaborate on the development and commercialization of ZALTRAP in all countries other than Japan, where we retained the exclusive right to develop and commercialize ZALTRAP. Sanofi 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 amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of ZALTRAP for intraocular delivery to the eye. In connection with this amendment, Sanofi made a $25.0 million non-refundable payment to us. In December 2005, we and Sanofi amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of ZALTRAP to include Japan. In connection with this amendment, Sanofi agreed to make a $25.0 million non-refundable up-front payment to us, which was received in January 2006.

In August 2012, the FDA approved ZALTRAP Injection for Intravenous Infusion, in combination with FOLFIRI, for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, and Sanofi commenced ZALTRAP sales in the United States. We received, and recorded as revenue in 2012, a $50.0 million substantive milestone payment from Sanofi upon FDA approval of ZALTRAP. We currently manufacture clinical and commercial supplies of ZALTRAP. In the future, Sanofi is expected to be responsible for manufacturing commercial supplies of ZALTRAP.

Under the collaboration agreement, as amended, we and Sanofi share co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to receive a percentage of approximately 35% on annual sales of ZALTRAP, subject to certain potential adjustments.

Under the collaboration agreement, as amended, agreed-upon worldwide ZALTRAP development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supplies, are funded

by Sanofi. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi for 50% of these development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option. In addition, if the collaboration becomes profitable, we will be obligated to reimburse Sanofi for 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement. As a result, we expect that, initially, our share of any ZALTRAP profits (including our percentage of sales of ZALTRAP in Japan) will be used to reimburse Sanofi for this repayment obligation. In particular, our contingent reimbursement obligation to Sanofi for ZALTRAP was approximately $446 million as of December 31, 2013.

Sanofi funded $9.8 million, $12.8 million, and $16.9 million, respectively, of our ZALTRAP development and other costs in 2013, 2012, and 2011. Our share of the loss from commercialization of ZALTRAP, representing our 50% share of ZALTRAP net product sales less cost of goods sold and shared commercialization and other expenses, was $30.8 million in 2013, $25.6 million in 2012, and $9.3 million in 2011. At December 31, 2013 and 2012, there was a net payable of $1.4 million and $2.7 million, respectively, to Sanofi in connection with the companies' ZALTRAP collaboration. In addition, the up-front payments from Sanofi 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 2013, 2012, and 2011, we recognized $5.5 million, $11.2 million, and $9.9 million per year of revenue, respectively, related to these up-front payments.

Sanofi 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 for 50% of ZALTRAP development expenses will terminate and we will retain all rights to ZALTRAP.

*Antibodies*

In November 2007, we and Sanofi entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement (each as amended). In connection with the execution of the discovery agreement in 2007, we received a non-refundable up-front payment of $85.0 million from Sanofi. Pursuant to the collaboration, Sanofi is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. In November 2009, we and Sanofi amended these collaboration agreements to expand and extend our antibody collaboration. Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery activities in 2010 through 2017. In 2010, as we scaled up our capacity to conduct antibody discovery activities, Sanofi funded $137.7 million of our preclinical research under the amended discovery agreement. The balance between that amount and $160 million was added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified through discovery research under the discovery agreement, Sanofi has the option to license rights to the candidate under the license agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10 million substantive milestone payment to us.

Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi, 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) are shared 80% by Sanofi and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse Sanofi for 50% of worldwide development expenses that were fully funded by Sanofi 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 for these development costs. In particular, our contingent reimbursement obligation to Sanofi in connection with the companies' antibody collaboration was approximately $879 million as of December 31, 2013. If Sanofi does not exercise its option to license rights to a particular drug candidate under the license agreement, we retain the exclusive right to develop and commercialize such drug candidate, and Sanofi will receive a royalty on sales, if any.

Sanofi will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing 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 funded $30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2013, 2012, and 2011, Sanofi funded $160.0 million, $181.9 million, and $161.9 million, respectively, of our expenses under the collaboration's discovery agreement and $295.4 million, $183.4 million, and $137.4 million, respectively, of our development and other costs under the license agreement. In addition, in 2013, we funded $17.6 million of Sanofi's Phase 3 development costs for alirocumab and sarilumab under the license agreement. The $85.0 million up-front payment received from Sanofi 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 addition, reimbursements by Sanofi of our costs to expand our manufacturing capacity were recorded to deferred revenue and are being recognized prospectively as collaboration revenue over the same period applicable to recognition of the $85.0 million up-front payment. In 2013, 2012, and 2011, we recognized $8.6 million, $8.6 million, and $8.2 million, of revenue, respectively, related to these deferred payments.

In connection with the antibody collaboration, in August 2008, we entered into a separate agreement with Sanofi, which extended through December 2012, to use our proprietary *VelociGene* technology platform to supply Sanofi with genetically modified mammalian models of gene function and disease. The agreement provided for minimum annual order quantities for the term of the agreement, for which we receive payments which will total $21.5 million.

With respect to our antibody collaboration with Sanofi, $106.1 million and $102.6 million was included in accounts receivable as of December 31, 2013 and 2012, respectively.

With respect to each antibody product which enters development under the license agreement, Sanofi 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 within thirty days of the date that Sanofi 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 has the right to terminate the amended discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, Sanofi 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 for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold Sanofi 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 entered into an investor agreement with us. This agreement, which was amended in January 2014, contains certain demand rights, “stand-still provisions”, and other restrictions, which are more fully described in Note 14 to our Consolidated Financial Statements. In addition, in October 2010, Sanofi purchased 1,017,401 shares of Common Stock in our underwritten public offering.

***Collaborations with Bayer HealthCare***

*EYLEA outside the United States*

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, EYLEA. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of $75.0 million. We also received from Bayer HealthCare a $20.0 million development milestone payment in 2007 (which, for the purpose of revenue recognition, was not considered substantive) and a $10.0 million substantive milestone development payment in each of 2010 and 2011.

Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the EU and other regions, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD and macular edema secondary to CRVO pending in other countries. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the companies will share equally in profits and losses from sales of EYLEA. We are entitled to receive a percentage of between 33.5% and 40.0% of EYLEA annual net sales in Japan. We are obligated to reimburse Bayer HealthCare out of our share of the collaboration profits (including our percentage of sales of EYLEA in Japan) for 50% of the agreed-upon development expenses that Bayer HealthCare has incurred 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. As a result, we expect that, initially, our share of any EYLEA profits outside the United States will be partly used to reimburse Bayer HealthCare for this repayment obligation. In particular, our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $276 million at December 31, 2013. We are obligated to use commercially reasonable efforts to supply clinical and commercial bulk product of EYLEA to Bayer HealthCare. Within the United States, we are responsible for commercialization of EYLEA and retain exclusive rights to all future profits from such commercialization in the United States.

In 2012, we received, and recognized as revenue, $15.0 million and $10.0 million substantive milestone payments from Bayer HealthCare upon receipt of marketing and pricing approval, respectively, in Japan for EYLEA for the treatment of wet AMD. In 2013, we received, and recognized as revenue, $15.0 million and $10.0 million substantive milestone payments from Bayer HealthCare upon receipt of marketing and pricing approval, respectively, for EYLEA for the treatment of macular edema secondary to CRVO outside the United States. In addition, in 2013, we received, and recognized as revenue, three $15.0 million sales milestone payments from Bayer HealthCare upon total aggregate sales of EYLEA outside the United States exceeding $200 million, $300 million, and $400 million, respectively, over a twelve-month period. We may earn up to $90 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels up to $1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of our EYLEA clinical data for a regulatory filing, we became eligible to receive up to $30 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to $200 million.

Under the terms of the agreement, since 2009, all agreed upon EYLEA development expenses incurred by both companies under a global development plan, and certain commercialization and other expenses, are shared equally, and profits or losses on sales of EYLEA outside the United States are also shared. In connection with our collaboration with Bayer HealthCare, we recognized $220.3 million, $70.1 million, and $43.1 million of collaboration revenue in 2013, 2012, and 2011, respectively. We also funded $15.3 million, $21.9 million, and $47.8 million of Bayer HealthCare's EYLEA development expenses in 2013, 2012, and 2011, respectively. At December 31, 2013 and 2012, $63.2 million and $2.8 million, respectively, were receivable from Bayer HealthCare in connection with the companies' EYLEA collaboration outside the United States. In addition, the $75.0 million up-front payment and the $20.0 million milestone payment received in 2007 from Bayer HealthCare were recorded to deferred revenue. In 2013, 2012, and 2011, we recognized $7.9 million, $7.9 million, and $9.4 million, respectively, of revenue related to these payments.

Based on the positive results of Phase 3 studies, we submitted a supplemental BLA for U.S. regulatory approval of EYLEA in DME in the fourth quarter of 2013; the target date for an FDA decision on the supplemental BLA is August 18, 2014. An application for marketing approval for the treatment of DME in the EU was also submitted during the fourth quarter of 2013.

In January 2014, Bayer HealthCare exercised its right to opt-in to the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with its opt-in, Bayer HealthCare will reimburse us for a defined share of the EYLEA global development costs that we have or will incur for the BRVO indication. In addition, profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared.

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 EYLEA.

*PDGFR-beta antibody outside the United States*

In January 2014, we entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to the collaboration for further development and commercialization outside the United States.

In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse us for 50% of the development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made a $2.5 million payment to us in January 2014. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to $17.5 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

If Bayer HealthCare exercises their right to opt-in to the collaboration, they will obtain exclusive commercialization rights to the product outside the United States, pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a $20 million opt-in payment to us, pay a $20 million development milestone to us upon receipt of the first marketing approval in the European Union or Japan, share profits from sales outside the United States equally with us, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. If Bayer HealthCare does not opt-in to the collaboration, we will have exclusive rights to develop and commercialize PDGFR-beta antibodies (except as a combination product with EYLEA) for use outside the United States.

We also have the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If we opt-out of the collaboration and Bayer HealthCare exercises its right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing a PDGFR-beta antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both us and Bayer HealthCare in writing.

***License Agreement with Astellas***

In July 2010, the non-exclusive license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to us in August 2010. In addition, Astellas will make a $130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

***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 to Cellectis with respect to our former *VelocImmune* license agreement with AstraZeneca, our current *VelocImmune* license agreement with Astellas, or our antibody collaboration with Sanofi. In addition, no royalties are payable to Cellectis 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 (as amended in November 2009).

***Royalty Agreement with Novartis Pharma AG***

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion. Canakinumab is marketed for the treatment of CAPS and gouty arthritis, and is in earlier stage development for other inflammatory diseases. We are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

***License and Settlement Agreements with Genentech***

On December 31, 2011, we entered into a Non-Exclusive License and Partial Settlement Agreement with Genentech (the Original Genentech Agreement) that covered making, using, and selling EYLEA in the United States for the prevention and treatment of human eye diseases and disorders in the United States, and ended the litigation relating to those matters. The Original Genentech Agreement provided for us to make payments to Genentech based on U.S. sales of EYLEA through May 7, 2016, the date the Davis-Smyth patents expire. Under the Original Genentech Agreement, we made a $60.0 million milestone payment when cumulative U.S. sales reached $400 million and are obligated to pay royalties of 4.75% on cumulative relevant sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative relevant sales of EYLEA over $3 billion.

Effective May 17, 2013, we entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the Amended Genentech Agreement), which amended the Original Genentech Agreement to now include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, we received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of human eye diseases and eye disorders through administration of EYLEA to the eye. Under the Amended Genentech Agreement, we are obligated to make payments to Genentech based on sales of EYLEA in the United States and EYLEA manufactured in the United States and sold outside the United States through May 7, 2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under our license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by Regeneron. Bayer HealthCare will share in all such payments based on the proportion of ex-U.S. EYLEA sales to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

Also on May 17, 2013, we entered into a Non-Exclusive License and Settlement Agreement (the ZALTRAP Agreement), with Genentech, Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC (the latter two entities, collectively, Sanofi) under which we and Sanofi received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than the prevention or treatment of eye diseases and eye disorders through administration to the eye. Under the terms of the ZALTRAP Agreement, payments are required to be made to Genentech based on sales of ZALTRAP in the United States and of ZALTRAP that is manufactured in the United States and sold outside the United States through May 7, 2016. A payment of $19 million is required to be made upon cumulative relevant sales of ZALTRAP reaching $200 million. In addition, royalty payments are required to be made to Genentech based upon 4.5% of cumulative relevant sales of ZALTRAP between $400 million and $1 billion and 6.5% of any cumulative relevant sales of ZALTRAP over $1 billion. All payments to Genentech under the ZALTRAP Agreement will be made by Sanofi, and we will share in all such payments.

***Tarrytown, New York Leases***

We lease approximately 664,000 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 space in two newly constructed buildings (Buildings A and B) that were completed during the third quarter of 2009 and approximately 131,000 square feet of additional space in a third newly constructed building (Building C), that was completed in early 2011. In April 2013, we executed an agreement related to approximately 360,000 square feet of space that we currently lease at our Tarrytown location, which extended the term of the lease from June 2024 to June 2029; the remaining space 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 271,000 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses.

In April 2013, we entered into a new lease agreement for approximately 297,000 square feet of additional new laboratory and office space to be constructed in two new buildings (Buildings D and E), which are expected to be completed in the second half of 2015, at our current Tarrytown, New York location. The term of the lease, which is expected to commence in mid-2014, is approximately 15 years and contains three renewal options to extend the term of the lease by five years each. The lease provides for (i) monthly payments over its term, which are expected to commence in 2015 and will be based on the landlord's costs of construction and tenant allowances, and (ii) additional charges for utilities, taxes, and operating expenses.

Certain premises under the lease are accounted for as operating leases. However, for Buildings A, B, C, D, and E (collectively, the Buildings) that we are or will be leasing, we are deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of FASB authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, we capitalize the landlord's costs of constructing these new facilities, offset by a corresponding facility lease obligation. As it relates to Buildings A, B, and C, we also recognized, as additional facility lease obligation, reimbursements from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation.

With respect to Buildings A and B, monthly lease payments commenced in August 2009, and the buildings were placed in service by us in September 2009. With respect to Building C, monthly lease payments commenced in January 2011, and the building was placed in service by us in February 2011.

At December 31, 2013 and 2012, the Buildings' facility lease obligation balance was $185.2 million and $160.8 million, respectively.

***Capital Expenditures***

Our cash expenditures for property, plant, and equipment totaled $156.3 million in 2013, $49.3 million in 2012, and $57.2 million in 2011.

In July 2013, we reached preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, subject to entering into definitive agreements as well as securing permits from the local government in Limerick. We intend to renovate this facility to accommodate and support our growth, primarily in connection with expanding our manufacturing capacity to support our global supply chain.

We expect to incur capital expenditures of approximately $350 to $425 million in 2014 primarily in connection with expanding our manufacturing facilities at our Rensselaer facility, tenant improvements primarily related to Buildings D and E at our leased Tarrytown facilities, purchasing and commencing renovations on the new Limerick facility described above (predicated on finalizing its purchase), and purchases of equipment.

***Offering of Convertible Senior Notes***

In October 2011, we issued $400.0 million aggregate principal amount of 1.875% convertible senior notes in a private placement. The notes were offered by the initial purchaser only to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933.

The notes pay interest semi-annually on April 1 and October 1, and will mature on October 1, 2016, unless earlier converted or repurchased. The notes are convertible, subject to certain conditions, into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our option. The initial conversion rate for the notes is 11.9021 shares of Common Stock (subject to adjustment in certain circumstances) per $1,000 principal amount of the notes, or a total of approximately 4,760,840 shares upon conversion, which is equal to an initial conversion price of approximately $84.02 per share. A holder of the notes may surrender their notes at their option any time prior to the close of business on the business day immediately preceding July 1, 2016, only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on December 31, 2011 (and only during such calendar quarter), if the last reported sale price of our Common Stock for at least 20 trading days

(whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any ten consecutive trading day period (the “measurement period”) in which the trading price, as defined, of the notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our Common Stock and the conversion rate on each such trading day; (iii) if we elect to issue to all or substantially all holders of our Common Stock any rights, options, or warrants (other than pursuant to a rights plan) entitling them for a period of not more than 60 calendar days after the record date for such issuance, to subscribe for or purchase shares of our Common Stock, at a price per share less than the average of the last reported sales prices of our Common Stock for the ten consecutive day period ending on, and including, the trading day immediately preceding the declaration date for such issuance; (iv) upon specified distributions to our shareholders; or (v) upon the occurrence of specified corporate transactions, such as a fundamental change (i.e., a change in control), or our Common Stock ceasing to be listed on at least one U.S. national securities exchange. On or after July 1, 2016, holders may convert their notes at the conversion rate at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date irrespective of the foregoing conditions. In the event that a fundamental change, as defined in the indenture under which the notes have been issued, occurs prior to maturity of the notes, the initial conversion rate may be increased to include additional shares upon conversion, or holders can require us to purchase from them all or a portion of their notes for 100% of the principal value plus any accrued and unpaid interest. Based on the reported sales prices of our Common Stock, the notes were able to be converted by holders as of December 31, 2013.

In connection with the offering of the convertible senior notes, we entered into convertible note hedge (call option) and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser. The convertible note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of our Common Stock that initially underlie the notes, and are intended to reduce the potential dilutive impact of the conversion feature of the notes. The convertible note hedge will terminate upon the earlier of the maturity date of the notes or the first day the notes are no longer outstanding. The warrant transactions have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of our Common Stock, at our option. The warrants expire at various dates during 2017.

The net proceeds from the convertible senior notes offering were $391.1 million after deducting the initial purchaser's discount and issuance costs. In addition, the net cost of the convertible note hedge transactions, after taking into account the proceeds received by us from the warrant transactions, was $23.7 million.

***Funding Requirements***

We expect continued growth in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, and commercialization of EYLEA. We believe that our existing capital resources, funds generated by anticipated EYLEA net product sales, and funding for reimbursement of development costs that we are entitled to receive under our collaboration agreements will enable us to meet our projected operating needs for the foreseeable future. As described above, research and development expenses that we incur in connection with our ZALTRAP and antibodies collaborations are generally funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed antibody drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. In addition, as described above, we and Bayer HealthCare share (i) agreed-upon development expenses that both companies incur in connection with our EYLEA collaboration, and (ii) development costs under the initial development plan in connection with our PDGFR-beta antibody collaboration.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2013. 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 | | | |
|---|---|---|---|---|---|
| *(In millions)* | Total | Less than one year | 1 to 3 years | 3 to 5 years | Greater than 5 years |
| Convertible senior notes [1] | $ 422.5 | $ 7.5 | $ 415.0 | — | — |
| Operating leases [2] | 117.6 | 10.9 | 19.8 | $ 19.0 | $ 67.9 |
| Purchase obligations [3] | 458.8 | 353.9 | 84.2 | 20.7 | — |
| Other long-term liabilities [4] | 304.3 | 17.7 | 36.6 | 38.2 | 211.8 |
| Total contractual obligations | $ 1,303.2 | $ 390.0 | $ 555.6 | $ 77.9 | $ 279.7 |

(1) Consists of $400.0 million aggregate principal amount of 1.875% convertible senior notes that mature on October 1, 2016, unless earlier converted or repurchased. The amounts in the table above assume the payment of interest on our convertible senior notes through their maturity date and the payment of the principal amount of the notes at their maturity date. Interest on the notes is payable semi-annually. The convertible senior notes will be convertible, subject to certain conditions, into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our option. As of December 31, 2013, the convertible senior notes were convertible under the terms of the indenture governing the notes.

(2) Excludes future contingent costs for utilities, real estate taxes, and operating expenses. In 2013, these costs were $11.5 million. See Note 13(a) to our Consolidated Financial Statements.

(3) 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.

(4) Represents payments with respect to facility lease obligations in connection with our lease of Buildings A, B, and C in Tarrytown, New York, as described under "Tarrytown, New York Leases" above. In addition to the estimated obligations in the table above, pursuant to a new lease agreement entered into in April 2013, there are two new buildings currently under construction (Buildings D and E). Rent payments on these buildings are expected to commence in 2015, and will be based on the landlord's costs of construction and tenant allowances. See Note 13(a) to our Consolidated Financial Statements.

As described above, in May 2013, we acquired from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 receptor and ligand in ophthalmology. With respect to PDGF antibodies, we made a $10.0 million up-front payment to Sanofi in May 2013 and a $5.0 million development milestone payment in January 2014, and are obligated to pay up to $35 million in potential additional development milestones and royalties on any future sales. With respect to Ang2 antibodies in ophthalmology, we also made a $10.0 million up-front payment to Sanofi in May 2013, and are obligated to pay a potential $5 million development milestone payment and royalties on any future sales.

Under our collaboration agreements with Sanofi and Bayer HealthCare, we and our collaborator will share profits and losses in connection with commercialization of drug products. Profits or losses under each collaboration are measured by calculating net sales less cost of goods sold and shared commercialization and other expenses. If the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse Sanofi and, in connection with EYLEA outside the United States, Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by Sanofi and Bayer HealthCare, respectively. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for our ZALTRAP collaboration with Sanofi and our EYLEA collaboration with Bayer HealthCare, our percentage on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. In particular, as of December 31, 2013, our contingent reimbursement obligation to Sanofi for ZALTRAP was approximately $446 million, while our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $276 million. Therefore, we expect that, initially, our share of profits from sales of ZALTRAP, and a portion of our share of profits from sales of EYLEA outside the United States, will be used to reimburse our collaborators for these obligations.

The amount we need to fund operations will depend on various factors, including revenues from net product sales, the potential regulatory approval and commercialization of our product candidates and new indications for our marketed products, and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need

to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with Sanofi and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above.

Our commercialization costs over the next few years will depend on, among other things, whether or not new indications for our marketed products or our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for such new indications or product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on sales of commercial products. In the future, if we are able to successfully develop, market, and sell EYLEA for other indications, or certain of our product candidates, we may be required to pay additional royalties or share the profits from such sales pursuant to our license or collaboration agreements. In addition, under the provisions of the PPACA and the Health Care and Education Reconciliation Act of 2010, a non-tax deductible annual fee (the Branded Prescription Drug Fee) is imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. This fee is allocated to companies, including Regeneron, based on their prior year market share of total branded prescription drug sales into these government programs.

As described above, in 2013, 2012, and 2011, we made cash payments of $195.1 million, $163.3 million, and $25.1 million, respectively, for employee tax obligations in connection with stock option exercises and vesting of restricted stock. Future cash requirements for such payments will depend on various factors, including the level of stock option grants and exercises and the sales prices of our Common Stock, and may continue to be substantial.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We may from time to time seek to retire or repurchase our outstanding debt (including our 1.875% convertible senior notes) through cash purchases or exchanges for equity or debt securities, in open market purchases, privately negotiated transactions, or otherwise. Such purchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved may be material.

Due to the amounts of our net operating loss and tax credit carry-forwards available for tax purposes, which totaled $450.4 million and $120.1 million, respectively, at December 31, 2013, we do not anticipate making significant cash payments for income taxes for at least the next twelve months.

In connection with our collaboration with Bayer HealthCare, we are entitled to receive up to $90 million in additional sales milestones based on total twelve-month sales of EYLEA outside the United States achieving certain specified levels up to $1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of our EYLEA clinical data for a regulatory filing, we became eligible to receive up to $30 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to $200 million.

Other than letters of credits totaling $1.6 million as of December 31, 2013, we have no off-balance sheet arrangements. A $3.4 million letter of credit was canceled in April 2013 in connection with the amendment of our Tarrytown lease, as described above. As of December 31, 2013, we had no other banking arrangements that provided short-term financing or lines of credit. In November 2013, we filed a shelf registration statement on Form S-3, to replace the shelf registration that expired in October 2013, registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. There is no assurance, however, that we will be able to complete any offerings of securities under this shelf or other registration statements. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets.

**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 investments in marketable securities, which consist primarily of corporate bonds, direct obligations of the U.S. government and its agencies, and other debt securities guaranteed by the U.S. government. 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 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $6.8 million and $4.9 million decrease in the fair value of our investment portfolio at December 31, 2013 and 2012, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities that we held at December 31, 2013 compared to the same period of 2012.

*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. During 2013, we recorded an other-than-temporary impairment charge of $2.9 million related to our investment in an equity security. During 2012 and 2011, we recorded no charges for other-than-temporary impairments of our marketable securities.

We are also subject to credit risk in connection with accounts receivable from our product sales of EYLEA and ARCALYST. These accounts receivable are due from three distributors and several specialty pharmacies, who are our customers. We have contractual payment terms with each of our customers, and we monitor our customers' financial performance and credit worthiness so that we can properly assess and respond to any changes in their credit profile. In addition, we may insure a portion of our accounts receivables within our overall risk management practices. During 2013, 2012, and 2011, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. At December 31, 2013 and 2012, one individual customer accounted for 75% and 80%, respectively, of our net trade accounts receivable balances.

*Foreign Exchange Risk*

As discussed further above, Bayer HealthCare markets EYLEA outside the United States and Sanofi markets ZALTRAP worldwide, and we share in profits and losses with these collaborators from such sales (including a percentage of sales in Japan). Therefore, significant changes in foreign exchange rates of the countries outside the United States where our product is sold by our collaboration partners can impact our operating results and financial condition. As sales outside the United States continue to grow, and as we expand our international operations, we will continue to assess potential steps, including foreign currency hedging and other strategies, to mitigate our foreign exchange risk.

**Item 8. Financial Statements and Supplementary Data**

The financial statements required by this Item are included on pages F-1 through F-40 of this report. The supplementary financial information required by this Item is included at page F-40 of this report.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”)) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

***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 as of December 31, 2013 using the framework in *Internal Control - Integrated Framework (1992)* 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, 2013. The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears under Item 15.

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, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our principal executive officer and principal 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.

## 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 2014 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 our website (http://www.regeneron.com) under the “Investors” heading on the “Corporate Governance” page. We may satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or a waiver from, a provision of our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions, by posting such information on our website where it is accessible through the same link noted above.

### Item 11. Executive Compensation

The information called for by this item will be included in our definitive proxy statement with respect to our 2014 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 2014 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 2014 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 2014 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 consolidated financial 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.

*3. Exhibits*

| Exhibit Number | Description |
|---|---|
| 3.1 | (m) – Restated Certificate of Incorporation. |
| 3.2 | (a) – By-Laws, as amended. |
| 4.1 | (aa) – Indenture, dated as of October 21, 2011, between Regeneron Pharmaceuticals, Inc. and Wells Fargo Bank, National Association, as Trustee. |
| 4.2 | (aa) – Form of 1.875% Convertible Senior Note due October 1, 2016. |
| 10.1 + | (z) – The Second Amended and Restated 2000 Long-Term Incentive Plan. |

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| 10.1.1 + | (b) | – 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. |
| 10.1.2 + | (b) | – 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. |
| 10.1.3 + | (c) | – 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. |
| 10.1.5 + | (q) | – 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. |
| 10.1.6 + | (q) | – 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. |
| 10.1.7 + | (y) | – 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 (revised). |
| 10.1.8 + | (y) | – 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 (revised). |
| 10.1.9 + | (dd) | – 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 (revised) |
| 10.1.10 + | | – Amendment No. 1 to the Second Amended and Restated 2000 Long-Term Incentive Plan. |
| 10.2 + | (p) | – Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D. |
| 10.3* + | (d) | – Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D. |
| 10.4 + | (ee) | – Offer Letter for Robert E. Landry effective September 9, 2013. |
| 10.5 + | (p) | – Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008. |
| 10.6* | (e) | – IL-1 License Agreement, dated June 26, 2002, by and among the Registrant, Immunex Corporation, and Amgen Inc. |
| 10.7* | (r) | – 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* | (r) | – Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009. |
| 10.9* | (f) | – Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant. |
| 10.9.1* | (d) | – Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 31, 2004. |
| 10.9.2 | (g) | – Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7, 2005. |
| 10.9.3* | (h) | – Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 21, 2005. |
| 10.9.4* | (h) | – 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* | (i) | – License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant. |
| 10.10.1* | (cc) | – Amendment Agreement, dated as of May 7, 2012, by and between Bayer HealthCare LLC and the Registrant. |
| 10.11 | (j) | – Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant. |
| 10.11.1* | (l) | – First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007. |
| 10.11.2 | (o) | – Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008. |
| 10.11.3 | (q) | – Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009. |
| 10.11.4 | (s) | – Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009. |

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| 10.11.5 | (t) | – Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010. |
| 10.11.6 | (w) | – Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010. |
| 10.11.7 | (y) | – Seventh Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of December 22, 2010. |
| 10.11.8 | (bb) | – Eighth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 1, 2011. |
| 10.11.9 | (bb) | – Ninth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 30, 2011. |
| 10.11.10 | (ff) | – Eleventh Amendment to Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated April 3, 2013. |
| 10.11.11 | (ff) | – Twelfth Amendment to Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated May 31, 2013. |
| 10.11.12 | (ff) | – Thirteenth Amendment to Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated May 31, 2013. |
| 10.12 | (ff) | – Mt. Pleasant Lease by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., dated April 3, 2013. |
| 10.13* | (k) | – Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant. |
| 10.13.1* | (x) | – Amendment to the Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 by and between Astellas Pharma Inc. and the Registrant, dated as of July 28, 2010. |
| 10.14* | (v) | – 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* | (v) | – 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. |
| 10.15.1* | (ff) | – First Amendment to Amended and Restated License and Collaboration Agreement by and between Regeneron Pharmaceuticals, Inc. and Aventis Pharmaceuticals Inc., dated May 1, 2013. |
| 10.16 | (m) | – 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 | (m) | – 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 | (u) | – 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* | (n) | – Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and the Registrant. |
| 10.19 | (aa) | – Purchase Agreement, dated as of October 18, 2011, between Regeneron Pharmaceuticals, Inc. and Goldman, Sachs & Co. |
| 10.20 | (aa) | – Master Terms and Conditions for Convertible Note Hedging Transactions, dated October 18, 2011, between Goldman, Sachs & Co. and Regeneron Pharmaceuticals, Inc. |
| 10.21 | (aa) | – Master Terms and Conditions for Base Warrants, dated October 18, 2011, between Goldman, Sachs & Co. and Regeneron Pharmaceuticals, Inc. |
| 10.22 | (aa) | – Master Terms and Conditions for Convertible Note Hedging Transactions, dated October 18, 2011, between Citibank, N.A. and Regeneron Pharmaceuticals, Inc. |
| 10.23 | (aa) | – Master Terms and Conditions for Base Warrants, dated October 18, 2011, between Citibank, N.A. and Regeneron Pharmaceuticals, Inc. |
| 10.24 | (aa) | – Master Terms and Conditions for Convertible Note Hedging Transactions, dated October 18, 2011, between Credit Suisse International and Regeneron Pharmaceuticals, Inc. |
| 10.25 | (aa) | – Master Terms and Conditions for Base Warrants, dated October 18, 2011, between Credit Suisse International and Regeneron Pharmaceuticals, Inc. |
| 10.26 | (aa) | – Master Terms and Conditions for Convertible Note Hedging Transactions, dated October 18, 2011, between Morgan Stanley & Co. International plc and Regeneron Pharmaceuticals, Inc. |

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| 10.27 | (aa) | – Master Terms and Conditions for Base Warrants, dated October 18, 2011, between Morgan Stanley & Co. International plc and Regeneron Pharmaceuticals, Inc. |
| 10.28* | (dd) | – Non-exclusive License and Partial Settlement Agreement with Genentech, Inc. |
| 10.28.1* | (ff) | – Amended and Restated Non-Exclusive License and Settlement Agreement by and between Genentech, Inc. and Regeneron Pharmaceuticals, Inc., effective May 17, 2013. |
| 10.28.2* | (ff) | – Non-Exclusive License and Settlement Agreement by and between Genentech, Inc., Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. Inc. and Sanofi U.S. LLC, effective May 17, 2013. |
| 10.28.3 | (ff) | – Agreement dated May 17, 2013 between Bayer Pharma AG, Bayer Australia Limited, Regeneron Pharmaceuticals, Inc., Regeneron UK Ltd and Genentech Inc. |
| 10.29* | (ff) | – Letter Agreement by and between Regeneron Pharmaceuticals, Inc. and Aventis Pharmaceuticals Inc., dated May 2, 2013. |
| 21.1 | | – Subsidiaries of Regeneron Pharmaceuticals, Inc. |
| 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 Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 31.2 | | – Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 32 | | – Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350. |
| 101 | | – Interactive Data File |
| 101.INS | | – XBRL Instance Document |
| 101.SCH | | – XBRL Taxonomy Extension Schema |
| 101.CAL | | – XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF | | – XBRL Taxonomy Extension Definition Document |
| 101.LAB | | – XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | | – XBRL Taxonomy Extension Presentation Linkbase |

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(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

(b) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.

(c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.

(d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2004, filed March 11, 2005.

(e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2002, filed August 13, 2002.

(f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2003, filed November 12, 2003.

(g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.

(h) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2005, filed February 28, 2006.

(i) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.

(j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.

(k) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.

(l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.

(m) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.

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| (n) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008. |
| (o) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008. |
| (p) | Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009. |
| (q) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009. |
| (r) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009. |
| (s) | Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009. |
| (t) | Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010. |
| (u) | Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2009, filed February 18, 2010. |
| (v) | Incorporated by reference from the Form 10-K/A for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2009, filed June 2, 2010. |
| (w) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2010, filed July 28, 2010. |
| (x) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2010, filed October 28, 2010. |
| (y) | Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2010, filed February 17, 2011. |
| (z) | Incorporated by reference from the Registration Statement on Form S-8 for Regeneron Pharmaceuticals, Inc., filed June 13, 2011. |
| (aa) | Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. filed October 24, 2011. |
| (bb) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2011, filed October 27, 2011. |
| (cc) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2012, filed July 25, 2012. |
| (dd) | Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2011, filed February 21, 2012. |
| (ee) | Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed September 12, 2013. |
| (ff) | Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2013, filed August 6, 2013. |

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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. |

**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.

Date: February 13, 2014

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

## 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 Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer, 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 | Date |
|---|---|---|
| /s/ LEONARD S. SCHLEIFER<br>Leonard S. Schleifer, M.D., Ph.D. | *President, Chief Executive Officer, and Director (Principal Executive Officer)* | February 13, 2014 |
| /s/ ROBERT E. LANDRY<br>Robert E. Landry | *Senior Vice President, Finance and Chief Financial Officer (Principal Financial Officer)* | February 13, 2014 |
| /s/ DOUGLAS S. McCORKLE<br>Douglas S. McCorkle | *Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)* | February 13, 2014 |
| /s/ GEORGE D. YANCOPOULOS<br>George D. Yancopoulos, M.D., Ph.D. | *Chief Scientific Officer, President, Regeneron Laboratories, and Director* | February 13, 2014 |
| /s/ P. ROY VAGELOS<br>P. Roy Vagelos, M.D. | *Chairman of the Board* | February 13, 2014 |
| /s/ CHARLES A. BAKER<br>Charles A. Baker | *Director* | February 13, 2014 |
| /s/ MICHAEL S. BROWN<br>Michael S. Brown, M.D. | *Director* | February 13, 2014 |
| /s/ ALFRED G. GILMAN<br>Alfred G. Gilman, M.D., Ph.D. | *Director* | February 13, 2014 |
| /s/ JOSEPH L. GOLDSTEIN<br>Joseph L. Goldstein, M.D. | *Director* | February 13, 2014 |
| /s/ CHRISTINE A. POON<br>Christine A. Poon | *Director* | February 13, 2014 |
| /s/ ARTHUR F. RYAN<br>Arthur F. Ryan | *Director* | February 13, 2014 |
| /s/ ERIC M. SHOOTER<br>Eric M. Shooter, Ph.D. | *Director* | February 13, 2014 |
| /s/ GEORGE L. SING<br>George L. Sing | *Director* | February 13, 2014 |
| /s/ MARC TESSIER-LAVIGNE<br>Marc Tessier-Lavigne, Ph.D. | *Director* | February 13, 2014 |

**REGENERON PHARMACEUTICALS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. and its subsidiaries at December 31, 2013 and December 31, 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in *Internal Control - Integrated Framework (1992)* 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.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 13, 2014

**REGENERON PHARMACEUTICALS, INC.**
**CONSOLIDATED BALANCE SHEETS**
***(In thousands, except share data)***

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 535,608 | $ 230,276 |
| Marketable securities | 158,376 | 77,819 |
| Accounts receivable - trade, net | 787,071 | 593,207 |
| Accounts receivable from Sanofi | 104,707 | 99,913 |
| Inventories | 70,354 | 28,638 |
| Deferred tax assets | 44,677 | 148,134 |
| Prepaid expenses and other current assets | 96,141 | 28,025 |
| Total current assets | 1,796,934 | 1,206,012 |
| | | |
| Restricted cash and marketable securities | — | 8,186 |
| Marketable securities | 389,891 | 271,230 |
| Property, plant, and equipment, at cost, net of accumulated depreciation and amortization | 526,983 | 379,940 |
| Deferred tax assets | 231,878 | 192,022 |
| Other assets | 5,327 | 23,100 |
| Total assets | $ 2,951,013 | $ 2,080,490 |
| **LIABILITIES and STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 250,896 | $ 111,345 |
| Deferred revenue from Sanofi, current portion | 12,815 | 17,022 |
| Deferred revenue - other, current portion | 34,185 | 33,809 |
| Facility lease obligations, current portion | 939 | 1,374 |
| Total current liabilities | 298,835 | 163,550 |
| | | |
| Deferred revenue from Sanofi | 76,522 | 76,520 |
| Deferred revenue - other | 107,677 | 131,822 |
| Facility lease obligations | 184,258 | 159,436 |
| Convertible senior notes | 320,315 | 296,518 |
| Other long-term liabilities | 11,330 | 7,259 |
| Total liabilities | 998,937 | 835,105 |
| | | |
| Commitments and contingencies (Note 13) | | |
| | | |
| 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 - 2,020,481 at December 31, 2013 and 2,069,187 at December 31, 2012 | 2 | 2 |
| Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued and outstanding - 97,666,814 at December 31, 2013 and 95,223,525 at December 31, 2012 | 97 | 95 |
| Additional paid-in capital | 2,045,857 | 1,763,508 |
| Accumulated deficit | (92,692) | (517,054) |
| Accumulated other comprehensive loss | (1,188) | (1,166) |
| Total stockholders' equity | 1,952,076 | 1,245,385 |
| Total liabilities and stockholders' equity | $ 2,951,013 | $ 2,080,490 |

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

**REGENERON PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**
***(In thousands, except per share data)***

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2013** | **2012** | **2011** |
| **Statements of Operations** | | | |
| Revenues: | | | |
| Net product sales | $ 1,425,839 | $ 858,093 | $ 44,686 |
| Sanofi collaboration revenue | 430,111 | 423,814 | 326,609 |
| Bayer HealthCare collaboration revenue | 220,289 | 70,099 | 43,072 |
| Technology licensing and other revenue | 28,506 | 26,471 | 31,457 |
| | 2,104,745 | 1,378,477 | 445,824 |
| Expenses: | | | |
| Research and development | 859,947 | 625,554 | 529,506 |
| Selling, general, and administrative | 329,415 | 210,755 | 117,261 |
| Cost of goods sold | 118,048 | 83,927 | 4,216 |
| Cost of collaboration manufacturing | 37,307 | 528 | — |
| | 1,344,717 | 920,764 | 650,983 |
| Income (loss) from operations | 760,028 | 457,713 | (205,159) |
| Other income (expense): | | | |
| Investment (expense) income | (231) | 2,012 | 3,549 |
| Interest expense | (46,437) | (45,304) | (21,282) |
| | (46,668) | (43,292) | (17,733) |
| Income (loss) before income taxes | 713,360 | 414,421 | (222,892) |
| Income tax (expense) benefit | (288,998) | 335,848 | 1,132 |
| Net income (loss) | $ 424,362 | $ 750,269 | $ (221,760) |
| Net income (loss) per share - basic | $ 4.33 | $ 7.92 | $ (2.45) |
| Net income (loss) per share - diluted | $ 3.81 | $ 6.75 | $ (2.45) |
| Weighted average shares outstanding - basic | 97,917 | 94,685 | 90,610 |
| Weighted average shares outstanding - diluted | 111,290 | 115,382 | 90,610 |
| **Statements of Comprehensive Income (Loss)** | | | |
| Net income (loss) | $ 424,362 | $ 750,269 | $ (221,760) |
| Other comprehensive income (loss): | | | |
| Unrealized (loss) gain on marketable securities, net of tax | (22) | 696 | 629 |
| Comprehensive income (loss) | $ 424,340 | $ 750,965 | $ (221,131) |

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

**REGENERON PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**For the Years Ended December 31, 2013, 2012, and 2011**
***(In thousands)***

| | Class A Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balance, December 31, 2010** | 2,182 | $ 2 | 87,238 | $ 87 | $1,575,780 | $ (1,045,563) | $ (2,491) | $ 527,815 |
| Issuance of Common Stock in connection with exercise of stock options | — | — | 3,770 | 4 | 43,611 | — | — | 43,615 |
| Common Stock tendered upon exercise of stock options in connection with employee tax obligations | — | — | (446) | — | (22,440) | — | — | (22,440) |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | — | — | 92 | — | 6,979 | — | — | 6,979 |
| Issuance of restricted Common Stock under Long-Term Incentive Plan | — | — | 16 | — | — | — | — | — |
| Restricted Common Stock tendered upon vesting in connection with employee tax obligations | — | — | (51) | — | (2,638) | — | — | (2,638) |
| Conversion of Class A Stock to Common Stock | (73) | — | 73 | — | — | — | — | — |
| Stock-based compensation charges | — | — | — | — | 56,609 | — | — | 56,609 |
| Equity component of convertible senior notes, net of issuance costs | — | — | — | — | 120,623 | — | — | 120,623 |
| Purchase of convertible note hedges | — | — | — | — | (117,500) | — | — | (117,500) |
| Issuance of warrants in connection with issuance of convertible senior notes | — | — | — | — | 93,800 | — | — | 93,800 |
| Net loss | — | — | — | — | — | (221,760) | — | (221,760) |
| Other comprehensive income, net of tax | — | — | — | — | — | — | 629 | 629 |
| **Balance, December 31, 2011** | 2,109 | 2 | 90,692 | 91 | 1,754,824 | (1,267,323) | (1,862) | 485,732 |
| Issuance of Common Stock in connection with exercise of stock options | — | — | 5,086 | 5 | 67,169 | — | — | 67,174 |
| Common Stock tendered upon exercise of stock options in connection with employee tax obligations | — | — | (878) | (1) | (112,833) | — | — | (112,834) |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | — | — | 64 | — | 6,325 | — | — | 6,325 |
| Issuance of restricted Common Stock under Long-Term Incentive Plan | — | — | 501 | — | — | — | — | — |
| Restricted Common Stock tendered upon vesting in connection with employee tax obligations | — | — | (282) | — | (50,466) | — | — | (50,466) |
| Conversion of Class A Stock to Common Stock | (40) | — | 40 | — | — | — | — | — |
| Stock-based compensation charges | — | — | — | — | 94,181 | — | — | 94,181 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Excess tax benefit from stock-based compensation | — | — | — | — | 4,308 | — | — | 4,308 |
| Net income | — | — | — | — | — | 750,269 | — | 750,269 |
| Other comprehensive income | — | — | — | — | — | — | 696 | 696 |
| **Balance, December 31, 2012** | 2,069 | 2 | 95,223 | 95 | 1,763,508 | (517,054) | (1,166) | 1,245,385 |
| Issuance of Common Stock in connection with exercise of stock options | — | — | 3,052 | 3 | 54,759 | — | — | 54,762 |
| Common Stock tendered upon exercise of stock options in connection with employee tax obligations | — | — | (644) | (1) | (179,422) | — | — | (179,423) |
| Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution | — | — | 38 | — | 5,718 | — | — | 5,718 |
| Issuance of restricted Common Stock under Long-Term Incentive Plan | — | — | 6 | — | — | — | — | — |
| Restricted Common Stock tendered upon vesting in connection with employee tax obligations | — | — | (57) | — | (15,664) | — | — | (15,664) |
| Conversion of Class A Stock to Common Stock | (49) | — | 49 | — | — | — | — | — |
| Stock-based compensation charges | — | — | — | — | 200,101 | — | — | 200,101 |
| Excess tax benefit from stock-based compensation | — | — | — | — | 216,857 | — | — | 216,857 |
| Net income | — | — | — | — | — | 424,362 | — | 424,362 |
| Other comprehensive loss | — | — | — | — | — | — | (22) | (22) |
| **Balance, December 31, 2013** | 2,020 | $ 2 | 97,667 | $ 97 | $2,045,857 | $ (92,692) | $ (1,188) | $ 1,952,076 |

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

**REGENERON PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
***(In thousands)***

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2013** | **2012** | **2011** |
| Cash flows from operating activities: | | | |
| Net income (loss) | $ 424,362 | $ 750,269 | $ (221,760) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization | 41,204 | 36,940 | 31,082 |
| Non-cash compensation expense | 198,399 | 94,157 | 56,094 |
| Non-cash interest expense | 23,061 | 22,925 | 5,101 |
| Other non-cash charges and expenses, net | 23,690 | 34,049 | 6,714 |
| Deferred taxes | 63,601 | (340,156) | — |
| Changes in assets and liabilities: | | | |
| Increase in Sanofi and trade accounts receivable | (198,658) | (590,085) | (21,118) |
| Increase in inventories | (47,956) | (28,932) | (14,094) |
| (Increase) decrease in prepaid expenses and other assets | (52,765) | (23,684) | 6,612 |
| Decrease in deferred revenue | (27,974) | (41,077) | (40,329) |
| Increase in accounts payable, accrued expenses, and other liabilities | 136,684 | 10,979 | 50,016 |
| Total adjustments | 159,286 | (824,884) | 80,078 |
| Net cash provided by (used in) operating activities | 583,648 | (74,615) | (141,682) |
| | | | |
| Cash flows from investing activities: | | | |
| Purchases of marketable securities | (577,278) | (470,393) | (240,391) |
| Sales or maturities of marketable securities | 378,146 | 439,209 | 426,356 |
| Purchase of restricted cash and marketable securities | — | (552) | (277) |
| Capital expenditures | (156,323) | (49,337) | (57,217) |
| Net cash (used in) provided by investing activities | (355,455) | (81,073) | 128,471 |
| | | | |
| Cash flows from financing activities: | | | |
| Payments in connection with facility and capital lease obligations | (2,024) | (2,203) | (1,667) |
| Proceeds from issuance of Common Stock | 57,393 | 63,549 | 43,587 |
| Payments in connection with Common Stock tendered for employee tax obligations | (195,087) | (163,300) | (25,078) |
| Excess tax benefit from stock-based compensation | 216,857 | 4,308 | — |
| Proceeds in connection with issuance of convertible notes, net of debt issuance costs | — | — | 391,107 |
| Proceeds in connection with issuance of warrants | — | — | 93,800 |
| Payment in connection with purchase of convertible note hedges | — | — | (117,500) |
| Net cash provided by (used in) financing activities | 77,139 | (97,646) | 384,249 |
| | | | |
| Net increase (decrease) in cash and cash equivalents | 305,332 | (253,334) | 371,038 |
| | | | |
| Cash and cash equivalents at beginning of period | 230,276 | 483,610 | 112,572 |
| | | | |
| Cash and cash equivalents at end of period | $ 535,608 | $ 230,276 | $ 483,610 |
| | | | |
| **Supplemental disclosure of cash flow information** | | | |
| Cash paid for interest | $ 23,842 | $ 21,946 | $ 14,725 |

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

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**For the years ended December 31, 2013, 2012, and 2011**
***(Unless otherwise noted, dollars in thousands, except per share data)***

## 1. Organization and Business

Regeneron Pharmaceuticals, Inc. and its subsidiaries (collectively, the “Company” or “Regeneron”) is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. The Company currently has three marketed products as follows:

- EYLEA® (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States, European Union ("EU"), Japan and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration ("wet AMD") and macular edema following central retinal vein occlusion ("CRVO"). The Company commenced sales of EYLEA for the treatment of wet AMD in November 2011 and for the treatment of macular edema following CRVO in September 2012, following receipt of regulatory approvals in the United States. Bayer HealthCare LLC commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals outside the United States, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Regeneron is collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Regeneron maintains exclusive rights to EYLEA in the United States and is entitled to all profits from any such sales.
- ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, known in the scientific literature as VEGF Trap, which is available in the United States, European Union, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan ("FOLFIRI"), for patients with metastatic colorectal cancer ("mCRC") that is resistant to or has progressed following an oxaliplatin-containing regimen. Marketing approval for ZALTRAP was received from the U.S. Food and Drug Administration ("FDA") in August 2012, and from the European Commission in February 2013. Regeneron and Sanofi globally collaborate on the development and commercialization of ZALTRAP.
- ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available 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. Marketing approval for ARCALYST for the treatment of CAPS was received from the FDA in 2008.

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 invests its excess cash primarily in marketable securities issued by investment grade institutions. 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 accumulated other comprehensive income (loss). If a 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 as a charge against income. As described under “Use of Estimates” below, 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.

***Accounts Receivable - Trade***

The Company's trade accounts receivable represents amounts due from its distributors and specialty pharmacies (collectively, the Company's "customers"), which are all located in the United States. The Company monitors the financial performance and credit worthiness of its large customers so that it can properly assess and respond to changes in their credit profile. The Company provides reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are written-off against the reserve.

***Inventories***

Inventories are stated at the lower of cost or estimated realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of goods sold to write down such unmarketable inventory to its estimated realizable value.

***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 | 10-35 years |
| Laboratory and other equipment | 3-10 years |
| Furniture and fixtures | 5 years |

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.

***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***

a. Product Revenue

Product sales consist of U.S. sales of EYLEA and ARCALYST. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss have passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, the Company has no further performance obligations, and returns can be reasonably estimated. The Company's written contracts with its customers stipulate product is shipped freight on board destination (FOB destination). The Company records revenue from product sales upon delivery to its customers.

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

The Company sells EYLEA in the United States to three distributors and several specialty pharmacies. The Company sells ARCALYST in the United States to two specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies generally take physical delivery of product. For EYLEA, the distributors and specialty pharmacies generally sell the product directly to healthcare providers, whereas for ARCALYST, the specialty pharmacies sell the product directly to patients.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, product returns, and other sales-related deductions. Calculating these provisions involves estimates and judgments. The Company reviews its estimates of rebates, chargebacks, and other applicable provisions each period and records any necessary adjustments in the current period's net product sales.

*Government Rebates and Chargebacks:* The Company estimates reductions to product sales for Medicaid and Veterans' Administration ("VA") programs, and for certain other qualifying federal and state government programs. Based upon the Company's contracts with government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, and estimated payer mix, the Company estimates and records an allowance for rebates and chargebacks. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for a current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, and invoices received for claims from prior quarters that have not been paid. The Company's reserves related to discounted pricing to VA, Public Health Services ("PHS"), and other institutions (collectively "qualified healthcare providers") represent the Company's estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices the Company charges to its customers (i.e., distributors and specialty pharmacies). The Company's customers charge the Company for the difference between what they pay for the products and the ultimate selling price to the qualified healthcare providers. The Company's reserve for this discounted pricing is based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

*Distribution-Related Fees:* The Company has written contracts with its customers that include terms for distribution-related fees. The Company estimates and records distribution and related fees due to its customers based on gross sales.

*Prompt Pay Discounts:* No prompt pay discounts are currently offered to the Company's customers on sales of EYLEA. In connection with sales of ARCALYST, the Company offers discounts to its customers for prompt payments. The Company estimates these discounts based on customer terms and historical experience, and expects that its customers will always take advantage of this discount. Therefore, the Company accrues 100% of the prompt pay discount that is based on the gross amount of each ARCALYST invoice, at the time of sale.

*Product Returns:* Consistent with industry practice, the Company offers its customers a limited right to return product purchased directly from the Company, which is principally based upon the product's expiration date. The Company will accept returns for three months prior to and up to six months after the product expiration date. Product returned is generally not resalable given the nature of the Company's products and method of administration. The Company develops estimates for product returns based upon historical experience, inventory levels in the distribution channel, shelf life of the product, and other relevant factors. The Company monitors product supply levels in the distribution channel, as well as sales by its customers of EYLEA to healthcare providers and ARCALYST to patients using product-specific data provided by its customers. If necessary, the Company's estimates of product returns may be adjusted in the future based on actual returns experience, known or expected changes in the marketplace, or other factors.

b. 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, payments for development activities, and sharing of profits or losses arising from the commercialization of products. 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. Although the Company did not enter into, or materially modify, any collaboration arrangements with multiple-deliverables during the years ended December 31, 2013, 2012, and 2011, any future arrangements with multiple deliverables will be divided into separate units of accounting if the deliverables in the arrangement meet certain criteria, including whether the delivered item or items has value to the collaborator on a standalone basis. 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 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 enhancement in value to the related development product candidate, (ii) the Company's performance and relative level of effort required to achieve the milestone, (iii) whether the milestone relates solely to past performance, and (iv) whether the milestone payment is considered reasonable relative to all of the deliverables and payment terms. Payments for achieving milestones which are not considered substantive are deferred 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, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities. 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 contains 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.

The Company may also be obligated to use commercially reasonable efforts to supply commercial bulk product to its collaborators. In such cases, the Company is reimbursed for its manufacturing costs as commercial product is shipped to its collaborators; however, recognition of such cost reimbursements as collaboration revenue is deferred until the product is sold by the Company's collaborators to third-party customers, at which time the Company's risk of inventory loss no longer exists. In addition, at that time, the related manufacturing costs for the sold product, which had been capitalized into inventory, are recognized by the Company.

Under the Company's collaboration agreements, product sales and cost of sales are recorded by the Company's collaborators. The Company shares in any profits or losses arising from the commercialization of collaboration products. The Company records its share of the profits or losses, representing net product sales less cost of goods sold and shared commercialization and other expenses, from commercialization of such products as collaboration revenue.

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. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize as revenue any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

c. *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 up-front 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. Up-front payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective license periods.

***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.

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 (“CROs”), 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/or the period over which clinical investigators or CROs 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 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 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, 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 expenses 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.

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

***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 Plan 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 considers 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 the Company's Common Stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the 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 assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities 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 it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Uncertain tax positions are accounted for in accordance with FASB authoritative guidance, which 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.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense.

***Per Share Data***

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income (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. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is 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, (ii) Common Stock to be issued upon the assumed conversion of the Company's convertible senior notes, which are included under the “if-converted method” when dilutive, and (iii) Common Stock to be issued upon the exercise of outstanding warrants, which are included under the “treasury stock method” when dilutive. The computation of diluted net loss per share for the year ended December 31, 2011 does not include common stock equivalents, since such inclusion would be antidilutive.

***Consolidation***

The consolidated financial statements include the accounts of Regeneron and its wholly-owned subsidiaries. Intercompany balances and transactions are eliminated in consolidation.

***Concentration of Credit Risk***

Financial instruments which potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents, certain financial instruments, and accounts receivable. A large portion of the Company's cash is held by a few major financial institutions. In accordance with the Company's policies, the Company mandates asset diversification and monitors exposure with its counterparties.

Accounts receivable from product sales of EYLEA and ARCALYST are due from three distributors and several specialty pharmacies, who are the Company's customers. The Company has contractual payment terms with each of its customers, and the Company monitors its customers' financial performance and credit worthiness so that it can properly assess and respond to any changes in their credit profile. In addition, the Company may insure a portion of its accounts receivables within its overall risk management practices. As of December 31, 2013 and 2012, there were no reserves against trade accounts receivable. In addition, during the years ended December 31, 2013, 2012, and 2011, the Company did not recognize any charges for write-offs of trade accounts receivable.

***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 provisions for product rebates, chargebacks, distribution-related fees, and returns; periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements; periods over which certain clinical trial costs are recognized; the Company's estimate of cumulative EYLEA sales through May 7, 2016 to determine a blended royalty rate as a basis for recognized royalty expense related to the Company's non-exclusive license with Genentech (see Note 13b); fair value of stock options; useful lives of property, plant, and equipment; inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value; capitalization of inventory costs associated with the Company's products prior to regulatory approval; deferred tax asset valuation allowance; and the assessment of uncertain tax positions.

With respect to the Company's collaborations with Sanofi and Bayer HealthCare:

- Included in Sanofi collaboration revenue is the Company's share of profits or losses from commercialization of ZALTRAP, which is provided by Sanofi, and includes an estimate of the Company's share of profits or losses for the most recent fiscal quarter.
- Included in Bayer HealthCare collaboration revenue is the Company's share of profits or losses from commercialization of EYLEA outside the United States, which is provided by Bayer HealthCare, and includes an estimate of the Company's share of profits or losses for the most recent fiscal quarter.
- Included in research and development expenses is the Company's share of development expenses incurred by its collaboration partners, Bayer HealthCare and Sanofi, including the Company's share of Bayer HealthCare and Sanofi estimated development expenses for the most recent fiscal quarter.

These estimates for the most recent period are adjusted, if necessary, in the subsequent period to reflect actual amounts.

***Reclassifications***

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

**3. Net Product Sales**

In November 2011, the Company received marketing approval from the FDA for EYLEA (aflibercept) Injection for the treatment of wet AMD. In September 2012, the Company received marketing approval from the FDA for EYLEA for the treatment of macular edema following CRVO. EYLEA net product sales totaled $1,408.7 million, $837.9 million, and $24.8 million for the years ended December 31, 2013, 2012, and 2011, respectively.

In February 2008, the Company received marketing approval from the FDA for ARCALYST Injection for Subcutaneous Use for the treatment of CAPS. ARCALYST net product sales totaled $17.1 million, $20.2 million, and $19.9 million for the years ended December 31, 2013, 2012, and 2011, respectively.

***(Unless otherwise noted, dollars in thousands, except per share data)***

For the years ended December 31, 2013, 2012, and 2011, the Company recorded 76%, 78%, and 42%, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales are recorded net of applicable provisions for rebates and chargebacks under governmental programs (including Medicaid), distribution-related fees, prompt pay discounts, product returns, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions for the years ended December 31, 2013 and 2012; such amounts were not significant during the year ended December 31, 2011.

| | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2011 | $ 585 | $ 1,451 | $ 182 | $ 2,218 |
| Provision related to current period sales | 14,153 | 45,028 | 3,070 | 62,251 |
| Credits/payments | (11,755) | (31,181) | (2,707) | (45,643) |
| Balance as of December 31, 2012 | 2,983 | 15,298 | 545 | 18,826 |
| Provision related to current period sales | 25,936 | 62,984 | 955 | 89,875 |
| Credits/payments | (24,519) | (58,619) | (962) | (84,100) |
| Balance as of December 31, 2013 | $ 4,400 | $ 19,663 | $ 538 | $ 24,601 |

## 4. 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. Significant agreements of this kind are described below.

### *a. Sanofi*

As described in Note 14, Sanofi owned a total of 15,816,953 shares of the Company's Common Stock as of December 31, 2013, principally purchased in connection with the companies' ZALTRAP and antibody collaborations described below. Total Company-incurred expenses associated with these Sanofi collaborations, which include reimbursable and non-reimbursable amounts and an allocable portion of general and administrative costs, were $600.1 million in 2013, $405.8 million in 2012, and $318.2 million in 2011.

*ZALTRAP (aflibercept)*

In September 2003, the Company entered into a collaboration agreement (the “ZALTRAP Agreement”) with Aventis Pharmaceuticals Inc. (predecessor to Sanofi U.S.), to jointly develop and commercialize ZALTRAP. In connection with this agreement, Sanofi 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 amended the ZALTRAP 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 made a $25.0 million non-refundable payment to Regeneron (the “Intraocular Termination Payment”). In December 2005, the Company and Sanofi amended the ZALTRAP Agreement to expand the territory in which the companies are collaborating on the development of ZALTRAP to include Japan. In connection with this amendment, Sanofi agreed to make a $25.0 million non-refundable up-front payment to the Company, which was received in January 2006.

Sanofi commenced sales of ZALTRAP Injection for Intravenous Infusion, in combination with FOLFIRI, for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in the third quarter of 2012 and in certain European and other countries in the first quarter of 2013. The Company earned, and recorded as revenue in 2012, a $50.0 million substantive milestone payment from Sanofi upon FDA approval of ZALTRAP. The Company currently manufactures clinical and commercial supplies of ZALTRAP.

Under the ZALTRAP Agreement, as amended, the Company and Sanofi share co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to

***(Unless otherwise noted, dollars in thousands, except per share data)***

receive a percentage of approximately 35% on annual sales of ZALTRAP in Japan, subject to certain potential adjustments. According to the terms of the ZALTRAP Agreement, the Company may also receive up to $350 million in additional substantive milestone payments upon receipt of specified marketing approvals.

Under the ZALTRAP Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi. If the collaboration becomes profitable, Regeneron will be obligated to reimburse Sanofi for 50% of these development expenses, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits, or at a faster rate at Regeneron's option. In connection with the January 2005 amendment to the ZALTRAP Agreement, the Intraocular Termination Payment of $25.0 million will also be subject to 50% reimbursement by Regeneron to Sanofi if the collaboration becomes profitable. In particular, the Company's total contingent reimbursement obligation to Sanofi for ZALTRAP was approximately $446 million as of December 31, 2013. Regeneron has the option to conduct additional pre-Phase III studies at its own expense.

Sanofi 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 for 50% of ZALTRAP development expenses will terminate, and the Company will retain all rights to ZALTRAP.

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 collaboration revenue related to ZALTRAP that the Company earned from Sanofi is detailed below:

| | Year ended December 31, | | |
|---|---|---|---|
| **Sanofi Collaboration Revenue - ZALTRAP** | **2013** | **2012** | **2011** |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | $ (30,810) | $ (25,634) | $ (9,321) |
| Substantive milestone payment | — | 50,000 | — |
| Reimbursement of Regeneron research and development expenses | 5,639 | 10,702 | 16,871 |
| Other | 9,682 | 13,268 | 9,932 |
| | $ (15,489) | $ 48,336 | $ 17,482 |

In connection with the ZALTRAP Agreement, (i) at December 31, 2013 and 2012, there was a net payable of $1.4 million and $2.7 million, respectively, to Sanofi, and (ii) deferred revenue at December 31, 2013 and 2012 was $18.2 million and $14.8 million, respectively.

*Antibodies*

In November 2007, the Company entered into a global, strategic collaboration (the “Antibody Collaboration”) with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies.

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the “Discovery Agreement”) and a License and Collaboration Agreement (the “License Agreement”). In connection with the execution of the Discovery Agreement in 2007, the Company received a non-refundable up-front payment of $85.0 million from Sanofi. In addition, under the Discovery Agreement, Sanofi is funding the Company's research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. In November 2009, the Company and Sanofi amended these collaboration agreements to expand and extend the Antibody Collaboration. Pursuant to the Discovery Agreement, as amended, Sanofi agreed to fund up to $160 million per year of the Company's research activities in 2010 through 2017. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified under the Discovery Agreement, Sanofi has the option to license rights to the candidate under the License Agreement. If it elects to do so, Sanofi will co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10 million substantive milestone payment to the Company. If Sanofi does not exercise its option to license rights to a

particular drug candidate under the License Agreement, the Company retains the exclusive right to develop and commercialize such drug candidate, and Sanofi will receive a royalty on sales, if any. The Company and Sanofi are currently co-developing seven 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 are funded by Sanofi, 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") are shared 80% by Sanofi and 20% by Regeneron. Consequently, commencing in 2013, the Company recognized as additional research and development expense $17.6 million of antibody development expenses that the Company was obligated to reimburse to Sanofi related to alirocumab and sarilumab. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse Sanofi for 50% of worldwide development expenses that were fully funded by Sanofi 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 for these development costs. In particular, the Company's contingent reimbursement obligation to Sanofi was approximately $879 million as of December 31, 2013.

Sanofi 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)/35% (Regeneron) and ending at 55% (Sanofi)/45% (Regeneron), and losses outside the United States at 55% (Sanofi)/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 funded $30.0 million of agreed-upon costs the Company incurred to expand its manufacturing capacity at its Rensselaer, New York facilities.

With respect to each antibody product which enters development under the License Agreement, Sanofi 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 within thirty days of the date that Sanofi 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 has the right to terminate the amended Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, Sanofi 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 for development costs out of any future profits from collaboration products will terminate. Upon expiration of the amended Discovery Agreement, Sanofi 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, which extended through December 2012, to use Regeneron's proprietary *VelociGene*® technology platform to supply Sanofi with genetically modified mammalian models of gene function and disease (the "*VelociGene* Agreement"). The *VelociGene* Agreement provided for minimum annual order quantities for the term of the agreement, for which the Company expects to receive payments totaling $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 May 2013, the Company acquired from Sanofi full exclusive rights to two families of novel antibodies invented at Regeneron and previously included in the Company's antibody collaboration with Sanofi. The Company acquired full rights to antibodies targeting the PDGF (platelet derived growth factor) family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the Ang2 (angiopoietin-2) receptor and ligand in ophthalmology. At the time of acquisition, antibodies

***(Unless otherwise noted, dollars in thousands, except per share data)***

to the PDGF receptor and Ang2 were in preclinical development for use in ophthalmology. With respect to PDGF antibodies, the Company made a $10.0 million up-front payment to Sanofi in the second quarter of 2013 and a $5.0 million development milestone payment in January 2014, and is obligated to pay up to $35 million in additional potential development milestones and royalties on any future sales. With respect to Ang2 antibodies in ophthalmology, the Company also made a $10.0 million up-front payment to Sanofi in the second quarter of 2013, and is obligated to pay a potential $5 million development milestone payment and royalties on any future sales.

In connection with the Antibody Collaboration, the collaboration revenue the Company recognized is detailed below:

| | Year ended December 31, | | |
|---|---|---|---|
| **Sanofi Collaboration Revenue - Antibody** | **2013** | **2012** | **2011** |
| Reimbursement of Regeneron research and development expenses | $ 453,489 | $ 365,245 | $ 299,281 |
| Up-front payments to Sanofi for acquisition of rights related to two antibodies | (20,000) | — | — |
| Other | 12,111 | 10,233 | 9,846 |
| | $ 445,600 | $ 375,478 | $ 309,127 |

In connection with the Antibody Collaboration, at December 31, 2013 and 2012, amounts receivable from Sanofi totaled $106.1 million and $102.6 million and deferred revenue was $71.2 million and $78.7 million, respectively.

***b. Bayer HealthCare LLC***

*EYLEA outside the United States*

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of EYLEA. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of $75.0 million. The Company also received from Bayer HealthCare a $20.0 million development milestone payment in 2007 (which, for the purpose of revenue recognition, was not considered substantive), a $20.0 million substantive development milestone payment in 2009, and a $10.0 million substantive milestone payment in each of 2010 and 2011 (both of which were earned in 2010).

Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012 following receipt of regulatory approvals in the EU and other regions, and for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013 following receipt of regulatory approvals in the EU and Japan. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the Company and Bayer HealthCare will share equally in profits and losses from sales of EYLEA. The Company is entitled to receive a percentage of between 33.5% and 40.0% of EYLEA annual sales in Japan. The Company is obligated to reimburse Bayer HealthCare out of its share of the collaboration profits (including the Company's percentage of sales of EYLEA in Japan) for 50% of the agreed upon development expenses that Bayer HealthCare has incurred 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. In particular, the Company's contingent reimbursement obligation to Bayer HealthCare was approximately $276 million as of December 31, 2013. Within the United States, the Company is responsible for commercialization of EYLEA and retains exclusive rights to all profits from such commercialization in the United States.

***(Unless otherwise noted, dollars in thousands, except per share data)***

In 2012, the Company earned and received a $15.0 million and $10.0 million substantive milestone payment related to marketing and pricing approval, respectively, of EYLEA for the treatment of wet AMD in Japan. In 2013, the Company earned and received a $15.0 million and a $10.0 million substantive milestone payment related to marketing and pricing approval, respectively, of EYLEA for the treatment of macular edema secondary to CRVO. In addition, in 2013, the Company earned and recorded as revenue, three $15.0 million sales milestone payments from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $200 million, $300 million, and $400 million, respectively, over a twelve-month period. The Company is eligible to receive up to $90 million in additional sales milestone payments if twelve-month sales of EYLEA outside the United States achieve certain specified levels up to $1 billion. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of the Company's EYLEA clinical data for a regulatory filing, the Company became eligible to receive up to $30 million in additional sales milestone payments if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels up to $200 million.

Since 2009, all agreed upon EYLEA development expenses incurred by the Company and Bayer HealthCare, under a global development plan, are being shared equally. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial bulk product of EYLEA.

In January 2014, Bayer HealthCare exercised its right to opt-in to the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following branch retinal vein occlusion ("BRVO"). In connection with its opt-in, Bayer HealthCare will reimburse Regeneron for a defined share of the EYLEA global development costs that the Company has incurred or will incur for the BRVO indication. In addition, profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared.

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 EYLEA.

The $75.0 million up-front licensing payment and the $20.0 million milestone payment received in 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 EYLEA development expenses that the Company incurs under the collaboration, the Company also recognizes, as collaboration revenue, the portion of those EYLEA development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon EYLEA development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's EYLEA development expenses that the Company is obligated to reimburse.

The collaboration revenue the Company earned from Bayer HealthCare is detailed below:

| | Year ended December 31, | | |
|---|---|---|---|
| **Bayer HealthCare Collaboration Revenue** | **2013** | **2012** | **2011** |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $ 101,494 | — | — |
| Sales and substantive development milestone payments | 70,000 | $ 25,000 | — |
| Cost-sharing of Regeneron EYLEA development expenses | 20,905 | 34,892 | $ 33,682 |
| Other | 27,890 | 10,207 | 9,390 |
| | $ 220,289 | $ 70,099 | $ 43,072 |

In addition, in 2013, 2012, and 2011, the Company recognized as additional research and development expense $15.3 million, $21.9 million, and $47.8 million, respectively, of EYLEA development expenses that the Company was obligated to reimburse to Bayer HealthCare.

In connection with the companies' collaboration, $63.2 million and $2.8 million was receivable from Bayer HealthCare at December 31, 2013 and 2012, respectively. In addition, at December 31, 2013 and 2012, deferred revenue from the Company's collaboration with Bayer HealthCare was $36.4 million and $36.5 million, respectively.

*PDGFR-beta antibody outside the United States*

In January 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, the Company will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to the collaboration for further development and commercialization outside the United States.

In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to the Company in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made a $2.5 million payment (which, for the purpose of revenue recognition, was not considered substantive) to the Company in January 2014. Further, in connection with the Company’s initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, the Company is eligible to receive up to $17.5 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

If Bayer HealthCare exercises its right to opt-in to the collaboration, they will obtain exclusive commercialization rights to the product outside the United States, pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a $20 million opt-in payment to the Company, pay a $20 million development milestone to the Company upon receipt of the first marketing approval in the European Union or Japan, share profits from sales outside the United States equally with the Company, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

Within the United States, the Company has exclusive commercialization rights and will retain all of the profits from sales. If Bayer HealthCare does not opt-in to the collaboration, the Company will have exclusive rights to develop and commercialize PDGFR-beta antibodies (except as a combination product with EYLEA) for use outside the United States.

The Company also has the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If the Company opts-out of the collaboration and Bayer HealthCare exercises their right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

Under the agreement, Bayer HealthCare has also agreed to a “standstill” provision, which prohibits Bayer HealthCare and its affiliates from seeking to influence the control of the Company or acquiring more than 20% of the Company's then outstanding shares of Class A Stock and Common Stock (taken together).

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing a PDGFR-beta antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both the Company and Bayer HealthCare in writing.

## 5. Technology Licensing Agreements

In March 2007, the Company entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a $20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to the Company in August 2010, which was deferred upon receipt and is being recognized as revenue ratably over the seven-year period beginning in mid-2011. In addition, Astellas will make a $130.0 million second payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune* technology. In connection with the Astellas license agreement, for each of the years ended December 31, 2013, 2012, and 2011, the Company recognized $23.6 million, $23.6 million, and $22.0 million of technology licensing revenue, respectively. In addition, deferred revenue at December 31, 2013 and 2012 was $104.6 million and $128.2 million, respectively.

In February 2007, the Company entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement. Regeneron remains entitled to receive mid-single digit royalties on any future sales of antibody products discovered by MedImmune/AstraZeneca using the *VelocImmune* technology.

## 6. Marketable Securities

Marketable securities at December 31, 2013 and December 31, 2012 consist of both debt securities issued by investment grade institutions as well as equity securities. The Company also held restricted marketable securities at December 31, 2012, which consisted of debt securities, as detailed below, that collateralized letters of credit and lease obligations. During 2013, these collateral requirements were rescinded, due to cancellation of lender collateralization requirements on the Company. As a result, during 2013, all formerly restricted marketable securities were reclassified as unrestricted on the Company's balance sheet which, for the purpose of the Company's Statement of Cash Flows, was treated as a non-cash investing transaction.

***(Unless otherwise noted, dollars in thousands, except per share data)***

The following tables summarize the Company's investments in marketable securities at December 31, 2013 and 2012.

| At December 31, 2013 | Amortized Cost Basis | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| *Unrestricted* | | | | |
| U.S. government and government agency obligations | $ 107,493 | $ 55 | $ (27) | $ 107,521 |
| Corporate bonds | 369,321 | 233 | (361) | 369,193 |
| Commercial paper | 23,891 | 53 | — | 23,944 |
| Municipal bonds | 36,935 | 45 | (59) | 36,921 |
| International government agency obligations | 2,007 | 1 | — | 2,008 |
| Certificates of deposit | 7,509 | 5 | — | 7,514 |
| Equity securities | 1,166 | — | — | 1,166 |
| | $ 548,322 | $ 392 | $ (447) | $ 548,267 |
| **At December 31, 2012** | | | | |
| *Unrestricted* | | | | |
| U.S. government and government agency obligations | $ 327,502 | $ 661 | $ (17) | $ 328,146 |
| Municipal bonds | 17,542 | — | (32) | 17,510 |
| Equity securities | 4,044 | — | (651) | 3,393 |
| | 349,088 | 661 | (700) | 349,049 |
| *Restricted* | | | | |
| U.S. government obligations | 5,902 | 9 | (2) | 5,909 |
| | $ 354,990 | $ 670 | $ (702) | $ 354,958 |

The Company classifies its debt securities based on their contractual maturity dates. The debt securities listed at December 31, 2013 mature at various dates through August 2024. The fair values of debt security investments by contractual maturity as of December 31, 2013 and 2012 consist of the following:

| | 2013 | 2012 |
|---|---|---|
| *Unrestricted* | | |
| Maturities within one year | $ 158,376 | $ 77,819 |
| Maturities after one year through five years | 383,410 | 267,837 |
| Maturities after five years through ten years | 4,138 | — |
| Maturities after ten years | 1,177 | — |
| | 547,101 | 345,656 |
| *Restricted* | | |
| Maturities within one year | — | 2,781 |
| Maturities after one year through five years | — | 3,128 |
| | — | 5,909 |
| | $ 547,101 | $ 351,565 |

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

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, 2013 and 2012.

| | Less than 12 Months | | 12 Months or Greater | | Total | |
|---|---|---|---|---|---|---|
| **At December 31, 2013** | **Fair Value** | **Unrealized Loss** | **Fair Value** | **Unrealized Loss** | **Fair Value** | **Unrealized Loss** |
| *Unrestricted* | | | | | | |
| U.S. government and government agency obligations | $ 49,241 | $ (27) | — | — | $ 49,241 | $ (27) |
| Corporate bonds | 176,140 | (361) | — | — | 176,140 | (361) |
| Municipal bonds | 14,431 | (59) | — | — | 14,431 | (59) |
| | $ 239,812 | $ (447) | — | — | $ 239,812 | $ (447) |
| **At December 31, 2012** | | | | | | |
| *Unrestricted* | | | | | | |
| U.S. government and government agency obligations | $ 44,738 | $ (17) | — | — | $ 44,738 | $ (17) |
| Municipal bonds | 17,510 | (32) | — | — | 17,510 | (32) |
| Equity securities | — | — | $ 3,393 | $ (651) | 3,393 | (651) |
| | 62,248 | (49) | 3,393 | (651) | 65,641 | (700) |
| *Restricted* | | | | | | |
| U.S government obligations | 1,194 | (2) | — | — | 1,194 | (2) |
| | $ 63,442 | $ (51) | $ 3,393 | $ (651) | $ 66,835 | $ (702) |

During the year ended December 31, 2013, the Company recorded an other-than-temporary impairment charge of $2.9 million related to its investment in an equity security. There were no other-than-temporary impairment charges recorded on the Company's investments during 2012 or 2011.

For the year ended December 31, 2013, total realized gains on sales of marketable securities were $1.0 million, and there were no realized losses. For the years ended December 31, 2012 and 2011, total realized gains and losses on sales of marketable securities were not material.

Changes in the Company's accumulated other comprehensive income (loss) for the years ended December 31, 2013, 2012, and 2011 related to unrealized gains and losses on available-for-sale marketable securities. In 2013, amounts reclassified from accumulated other comprehensive income (loss) into investment (expense) income in the Company's Statements of Operations were the impairment charge on the equity security and realized gains discussed above. Such amounts were not material for the years ended December 31, 2012 and 2011.

***(Unless otherwise noted, dollars in thousands, except per share data)***

## 7. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis, at December 31, 2013 and 2012, consist of the following:

| | | Fair Value Measurements at Reporting Date Using | |
|---|---|---|---|
| **At December 31, 2013** | **Fair Value** | **Quoted Prices in Active Markets for Identical Assets (Level 1)** | **Significant Other Observable Inputs (Level 2)** |
| *Unrestricted* | | | |
| Available-for-sale marketable securities: | | | |
| U.S. government and government agency obligations | $ 107,521 | — | $ 107,521 |
| Corporate bonds | 369,193 | — | 369,193 |
| Commercial paper | 23,944 | — | 23,944 |
| Municipal bonds | 36,921 | — | 36,921 |
| International government agency obligations | 2,008 | — | 2,008 |
| Certificates of deposit | 7,514 | — | 7,514 |
| Equity securities | 1,166 | $ 1,166 | — |
| | $ 548,267 | $ 1,166 | $ 547,101 |
| | | | |
| **At December 31, 2012** | | | |
| *Unrestricted* | | | |
| Available-for-sale marketable securities: | | | |
| U.S. government and government agency obligations | $ 328,146 | — | $ 328,146 |
| Municipal bonds | 17,510 | — | 17,510 |
| Equity securities | 3,393 | $ 3,393 | — |
| | 349,049 | 3,393 | 345,656 |
| *Restricted* | | | |
| Available-for-sale marketable securities: | | | |
| U.S. government obligations | 5,909 | — | 5,909 |
| | $ 354,958 | $ 3,393 | $ 351,565 |

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. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities in 2013, 2012, and 2011.

During part of 2012, the Company held one Level 3 marketable security whose cost basis was zero, as the security had been fully impaired prior to 2012. In 2013, the Company sold this Level 3 marketable security and realized a gain on its sale which was not material. There were no purchases or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the years ended December 31, 2013 and 2012. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the years ended December 31, 2013 and 2012.

***(Unless otherwise noted, dollars in thousands, except per share data)***

As of December 31, 2013 and 2012, the Company had $400.0 million in aggregate principal amount of 1.875% convertible senior notes that will mature on October 1, 2016 unless earlier converted or repurchased. The fair value of the outstanding convertible senior notes was estimated to be $1,327.2 million and $843.2 million as of December 31, 2013 and 2012, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

## 8. Inventories

Inventories consist of the following:

| | As of December 31, | |
|---|---|---|
| | 2013 | 2012 |
| Raw materials | $ 9,120 | $ 4,862 |
| Work-in-process | 35,868 | 14,656 |
| Finished goods | 14,352 | 2,570 |
| Deferred costs | 11,014 | 6,550 |
| | $ 70,354 | $ 28,638 |

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. In 2013, 2012, and 2011, cost of goods sold included inventory write-downs and reserves totaling $9.1 million, $17.0 million, and $0.5 million, respectively.

## 9. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

| | As of December 31, | |
|---|---|---|
| | 2013 | 2012 |
| Land | $ 2,768 | $ 2,117 |
| Building and improvements | 343,363 | 328,173 |
| Leasehold improvements | 26,370 | 10,576 |
| Construction-in-progress | 142,370 | 25,076 |
| Laboratory and other equipment | 189,543 | 159,026 |
| Furniture, computer and office equipment, and other | 44,186 | 35,485 |
| | 748,600 | 560,453 |
| Less, accumulated depreciation and amortization | (221,617) | (180,513) |
| | $ 526,983 | $ 379,940 |

Depreciation and amortization expense on property, plant, and equipment amounted to $41.2 million, $36.9 million, and $31.1 million for the years ended December 31, 2013, 2012, and 2011, respectively. In addition, during 2013 and 2012, the Company incurred non-cash charges of $0.5 million and $2.8 million, respectively, in connection with disposals and retirements of fixed assets. There were no material non-cash charges in connection with disposals and retirements of fixed assets in 2011.

Included in property, plant, and equipment at December 31, 2013 and December 31, 2012 were $0.7 million and $3.6 million of leased equipment under capital leases, respectively, and related accumulated amortization was $0.2 million and $1.1 million at December 31, 2013 and December 31, 2012, respectively.

Property, plant, and equipment at December 31, 2013 and 2012 included $111.1 million and $86.2 million, respectively, of costs incurred by the Company's landlord to construct laboratory and office facilities in Tarrytown, New York. See Note 13a.

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

## 10. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

| | As of December 31, | |
|---|---|---|
| | 2013 | 2012 |
| Accounts payable | $ 61,936 | $ 38,934 |
| Accrued payroll and related costs | 69,429 | 19,987 |
| Accrued clinical trial expense | 23,654 | 10,985 |
| Accrued sales-related charges, deductions, and royalties | 66,855 | 21,870 |
| Other accrued expenses and liabilities | 29,022 | 19,569 |
| | $ 250,896 | $ 111,345 |

## 11. Deferred Revenue

Deferred revenue consists of the following:

| | As of December 31, | |
|---|---|---|
| | 2013 | 2012 |
| Current portion: | | |
| Received or receivable from Sanofi (see Note 4a) | $ 12,815 | $ 17,022 |
| Received or receivable from Bayer HealthCare (see Note 4b) | 9,738 | 9,212 |
| Received for technology license agreement (see Note 5) | 23,572 | 23,572 |
| Other | 875 | 1,025 |
| | $ 47,000 | $ 50,831 |
| Long-term portion: | | |
| Received or receivable from Sanofi (see Note 4a) | $ 76,522 | $ 76,520 |
| Received or receivable from Bayer HealthCare (see Note 4b) | 26,683 | 27,256 |
| Received for technology license agreement (see Note 5) | 80,994 | 104,566 |
| | $ 184,199 | $ 208,342 |

## 12. Convertible Debt

In October 2011, the Company issued $400.0 million aggregate principal amount of 1.875% convertible senior notes (the “Notes”) in a private placement. The net proceeds from the Notes offering were $391.1 million after deducting the initial purchaser's discount and issuance costs.

The Notes pay interest semi-annually on April 1 and October 1, which began April 1, 2012, and will mature on October 1, 2016 unless earlier converted or repurchased. The Notes are convertible, subject to certain conditions, into cash, shares of the Company's Common Stock, or a combination of cash and shares of Common Stock, at the Company's option. The initial conversion rate for the Notes is 11.9021 shares of Common Stock (subject to adjustment in certain circumstances) per $1,000 principal amount of the Notes, or a total of approximately 4,760,840 shares upon conversion, which is equal to an initial conversion price of approximately $84.02 per share. A holder of the Notes may surrender its Notes at its option any time prior to the close of business on the business day immediately preceding July 1, 2016, only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on December 31, 2011 (and only during such calendar quarter), if the last reported sale price of the Company's Common Stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion

***(Unless otherwise noted, dollars in thousands, except per share data)***

price on each applicable trading day; (ii) during the five business day period after any ten consecutive trading day period (the "measurement period") in which the trading price, as defined, of the Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's Common Stock and the conversion rate on each such trading day; (iii) if the Company elects to issue to all or substantially all holders of its Common Stock any rights, options or warrants (other than pursuant to a rights plan) entitling them for a period of not more than 60 calendar days after the record date for such issuance, to subscribe for or purchase shares of the Company's Common Stock, at a price per share less than the average of the last reported sales prices of the Company's Common Stock for the ten consecutive day period ending on, and including, the trading day immediately preceding the declaration date for such issuance; (iv) upon specified distributions to the Company's shareholders; or (v) upon the occurrence of specified corporate transactions, such as a fundamental change (i.e., a change in control), or the Company's Common Stock ceasing to be listed on at least one U.S. national securities exchange. On or after July 1, 2016, holders may convert their Notes at the conversion rate at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date irrespective of the foregoing conditions. In the event that a fundamental change, as defined in the indenture under which the Notes have been issued, occurs prior to maturity of the Notes, the initial conversion rate may be increased to include additional shares upon conversion, or holders can require the Company to purchase from them all or a portion of their Notes for 100% of the principal value plus any accrued and unpaid interest. Based on the reported sales prices of the Company's Common Stock, the Notes were able to be converted by holders as of December 31, 2013.

The Company has reserved sufficient shares of its Common Stock to satisfy the conversion requirements related to the Notes. The Company may not redeem the Notes prior to their maturity date.

As of December 31, 2013, the "if converted value" exceeded the principal amount of the Notes by $910.4 million.

In accordance with accounting guidance for debt with conversion and other options, the Company accounted for the liability and equity components of the Notes separately. The estimated fair value of the liability component at the date of issuance was $271.1 million, and was computed based on the fair value of similar debt instruments that do not include a conversion feature. The equity component of $120.9 million was recognized as a debt discount and represents the difference between the $392.0 million of gross proceeds from the issuance of the Notes and the $271.1 million estimated fair value of the liability component at the date of issuance. The debt discount is amortized over the expected life of a similar liability without the equity component. The Company determined this expected life to be equal to the term of the Notes, resulting in an amortization period ending October 1, 2016. The effective interest rate used to amortize the debt discount is approximately 10.2%, which was based on the Company's estimated non-convertible borrowing rate as of the date the Notes were issued.

Issuance costs of $0.9 million related to the issuance of the Notes were allocated to the liability and equity components in proportion to the allocation of the proceeds and accounted for as capitalized debt issuance costs and equity issuance costs, respectively.

The net carrying amount of the liability component of the Notes consists of the following:

| | As of December 31, | |
|---|---|---|
| | **2013** | **2012** |
| Total convertible senior notes - par | $ 400,000 | $ 400,000 |
| Unamortized discount | (79,685) | (103,482) |
| | $ 320,315 | $ 296,518 |

Total interest expense associated with the Notes, net of capitalized interest as applicable (see Note 21), consisted of the following for the years ended December 31, 2013, 2012, and 2011:

| | **2013** | **2012** | **2011** |
|---|---|---|---|
| Contractual coupon interest rate | $ 7,230 | $ 7,503 | $ 1,455 |
| Amortization of discount and note issuance costs | 22,980 | 21,623 | 3,944 |
| | $ 30,210 | $ 29,126 | $ 5,399 |

In connection with the offering of the Notes in October 2011, the Company entered into convertible note hedge ("call option") and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser of the Notes. The convertible

note hedge transactions cover, subject to customary anti-dilution adjustments, the number of shares of the Company's Common Stock that initially underlie the Notes, and are intended to reduce the potential dilutive impact of the conversion feature of the Notes. The convertible note hedge will terminate upon the earlier of the maturity date of the Notes or the first day the Notes are no longer outstanding. The Company paid $117.5 million for the convertible note hedge, which was recorded as a reduction to additional paid-in capital.

The warrant transactions have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of the Company's Common Stock, at the Company's option. The warrant transactions have a dilutive effect to the extent that the market price per share of the Company's Common Stock exceeds the applicable strike price of the warrants. Proceeds received from the warrant transactions totaled $93.8 million and were recorded as additional paid-in capital. The warrants expire at various dates during 2017.

The convertible note hedge and warrants are both considered indexed to the Company's Common Stock and classified as equity; therefore, the convertible note hedge and warrants are not accounted for as derivative instruments. The Company has reserved sufficient shares of its Common Stock to satisfy the potential settlement of the warrants.

## 13. 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, as well as an April 2013 lease agreement, as further described below.

The facilities leased by the Company under the December 2006 lease include (i) space in previously existing buildings, (ii) newly constructed space in two buildings (“Buildings A and B”) that was completed in the third quarter of 2009 and, (iii) under a December 2009 amendment to the lease, additional newly constructed space in a third building (“Building C”) that was completed in the first quarter of 2011. In April 2013, the Company executed an agreement related to Buildings A, B, and C, which extended the term of the lease of those facilities from June 2024 to June 2029; the remaining facilities under the lease will expire in June 2024. The lease contains three renewal options to extend the term of the lease by five years each, escalations at 2.5% per annum, and early termination options for various portions of the space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses.

In April 2013, the Company entered into a lease agreement for additional laboratory and office space to be constructed in two new buildings ("Buildings D and E"), which are expected to be completed in the second half of 2015, at the Company's current Tarrytown, New York location. The initial term of the lease, which is expected to commence in mid-2014, is approximately 15 years and contains three renewal options to extend the term of the lease by five years each. The lease provides for (i) monthly payments over its term, which will be based on the landlord's costs of construction and tenant allowances, and (ii) additional charges for utilities, taxes, and operating expenses.

Certain premises under the December 2006 lease are accounted for as operating leases. However, for Buildings A, B, C, D, and E (collectively, the "Buildings") 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. Consequently, in addition to capitalizing the tenant improvements, the Company capitalizes the landlord's costs of constructing these new facilities, offset by a corresponding lease obligation on the Company's balance sheet.

The Company also leases certain other laboratory, office, and storage space and equipment under operating and capital leases which expire at various times through 2022.

***(Unless otherwise noted, dollars in thousands, except per share data)***

*Commitments under Operating Leases*

The estimated future minimum noncancelable lease commitments under operating leases are as follows:

| December 31, | Facilities | Equipment | Total |
|---|---|---|---|
| 2014 | $ 8,765 | $ 2,169 | $ 10,934 |
| 2015 | 9,348 | 505 | 9,853 |
| 2016 | 9,895 | 24 | 9,919 |
| 2017 | 9,429 | — | 9,429 |
| 2018 | 9,606 | — | 9,606 |
| Thereafter | 67,849 | — | 67,849 |
| | $ 114,892 | $ 2,698 | $ 117,590 |

Rent expense under operating leases was:

| Year Ended December 31, | Facilities | Equipment | Total |
|---|---|---|---|
| 2013 | $ 9,404 | $ 471 | $ 9,875 |
| 2012 | 7,428 | 601 | 8,029 |
| 2011 | 7,191 | 599 | 7,790 |

In addition to its rent expense under operating leases, and payments under facility lease obligations (see below), for various facilities, the Company paid rental charges for utilities, real estate taxes, and operating expenses of $11.5 million, $10.9 million, and $9.3 million for the years ended December 31, 2013, 2012, and 2011, respectively.

*Commitments under Capital Leases*

In 2011, the Company entered into capital leases in connection with acquisitions of new equipment, which expire at various times through 2014. The lease obligations were collateralized with marketable debt securities totaling $3.2 million at December 31, 2012; such collateral was classified as restricted cash and marketable securities. During 2013, the requirement for the Company to collateralize these capital leases was rescinded. The Company did not enter into capital leases in 2013 or 2012.

At the end of the lease term, the Company is required to purchase the leased equipment for a nominal amount defined in the lease agreement. At December 31, 2013 and 2012, capital lease obligations totaled $0.1 million and $1.3 million, respectively, and were included in other liabilities. The estimated future minimum noncancelable lease commitments under capital leases at December 31, 2013 were not material.

*Facility Lease Obligations*

As described above, based upon various factors, including the Company's involvement in the construction of the Buildings and its responsibility for directly paying for a substantial portion of tenant improvements, the Company is deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of FASB authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, the Company capitalizes the landlord's costs of constructing these new facilities, offset by a corresponding lease obligation on the Company's balance sheet. The Company also recognizes, as additional facility lease obligation, reimbursements from the Company's landlord for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. The Company allocates a portion of its lease payments on these facilities between the Buildings and the land on which the Buildings are constructed, based on the initial estimated relative fair values of the land and Buildings. The land element of the lease is treated for accounting purposes as an operating lease.

With respect to Buildings A and B, monthly lease payments commenced in August 2009, the buildings were placed in service by the Company in September 2009, and the imputed interest rate applicable to the Company's facility lease obligation is approximately 11%. With respect to Building C, monthly lease payments commenced in January 2011, the building was placed in service by the Company in February 2011, and the imputed interest rate applicable to the Company's facility lease obligation is approximately 9%. In 2013, 2012, and 2011, the Company recognized $16.2 million, $16.0 million, and $15.6 million,

***(Unless otherwise noted, dollars in thousands, except per share data)***

respectively, of interest expense in connection with the Buildings A and B and the Building C facility lease obligations. At December 31, 2013 and 2012, the Buildings A and B facility lease obligation balance was $111.2 million and $112.0 million, respectively, and the Building C facility lease obligation balance was $49.1 million and $48.8 million, respectively.

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2013, are as follows:

| December 31, | Buildings A and B | Building C | Total |
|---|---|---|---|
| 2014 | $ 13,288 | $ 4,438 | $ 17,726 |
| 2015 | 13,545 | 4,562 | 18,107 |
| 2016 | 13,809 | 4,689 | 18,498 |
| 2017 | 14,079 | 4,818 | 18,897 |
| 2018 | 14,356 | 4,951 | 19,307 |
| Thereafter | 146,667 | 65,074 | 211,741 |
| | $ 215,744 | $ 88,532 | $ 304,276 |

Commencing in the second quarter of 2013, the Company began capitalizing the landlord's costs of constructing Buildings D and E, which totaled $25.0 million at December 31, 2013, and recognized a corresponding facility lease obligation. Rent expense in connection with the land element of these new facilities also commenced in the second quarter of 2013 and is recorded as a deferred liability until lease payments commence, which is expected to be in 2015. Rent payments will be based on the landlord's costs of construction and tenant allowances, and will include additional charges for utilities, taxes, and operating expenses.

***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 1% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

As described in Note 4, the Company has contingent reimbursement obligations to its collaborators Sanofi and Bayer HealthCare once the applicable collaboration becomes profitable.

In December 2011, the Company and Genentech, a member of the Roche Group, entered into a Non-Exclusive License and Partial Settlement Agreement (the “Original Genentech Agreement”) that covered making, using, and selling EYLEA for the prevention of human eye diseases and disorders in the United States, and ended the litigation relating to those matters. Pursuant to the Original Genentech Agreement, the Company received a non-exclusive license to certain patents relating to VEGF receptor proteins, known as the Davis-Smyth patents, and other technology patents. The Original Genentech Agreement provided for the Company to make payments to Genentech based on U.S. sales of EYLEA commencing upon FDA approval of EYLEA in November 2011 through May 7, 2016. The Company made a one-time, non-refundable $60.0 million payment during 2012 upon cumulative U.S. sales of EYLEA reaching $400 million, and is obligated to pay royalties of 4.75% on cumulative U.S. sales of EYLEA between $400 million and $3 billion and 5.5% on any cumulative U.S sales of EYLEA over $3 billion. As the Company records net product sales of EYLEA, the Company is recognizing expense in connection with the Genentech Agreement using a blended mid-single digit royalty rate that reflects both the $60.0 million payment and the royalties payable on cumulative sales and that is based upon the Company's estimate of cumulative EYLEA sales through May 7, 2016.

Effective May 17, 2013, the Company entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the "Amended Genentech Agreement"), which amended the Original Genentech Agreement to now include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, the Company received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of eye diseases and eye disorders in a human through administration of EYLEA to the eye. Under the Amended Genentech Agreement, the Company is obligated to make payments to Genentech based on sales of EYLEA in the United States, and EYLEA manufactured in the United States and sold outside the United States, through May 7,

2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under the Company's license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by the Company. Bayer HealthCare will share in all such payments based on the proportion of ex-U.S. EYLEA sales to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

Also on May 17, 2013, the Company entered into a Non-Exclusive License and Settlement Agreement (the "ZALTRAP Settlement Agreement") with Genentech and Sanofi under which the Company and Sanofi received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than the prevention or treatment of eye diseases and eye disorders through administration to the eye. Under the terms of the ZALTRAP Settlement Agreement, payments are required to be made to Genentech based on sales of ZALTRAP in the United States and of ZALTRAP that is manufactured in the United States and sold outside the United States through May 7, 2016. A payment of $19 million is required to be made upon cumulative relevant sales of ZALTRAP reaching $200 million. In addition, royalty payments are required to be made to Genentech based upon 4.5% of cumulative relevant sales of ZALTRAP between $400 million and $1 billion and 6.5% of any cumulative relevant sales of ZALTRAP over $1 billion. All payments to Genentech under the ZALTRAP Settlement Agreement will be made by Sanofi, and the Company will share in all such payments.

The Company recognizes royalty expense based on product sales of its commercial products under various licensing agreements, including, for EYLEA sales both inside and outside of the United States, the Genentech agreements described above. For the years ended December 31, 2013, 2012, and 2011, royalties on product sales totaled $128.1 million, $59.5 million, and $3.2 million, respectively.

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 to Cellectis with respect to the Company's *VelocImmune* license agreements with AstraZeneca and Astellas or the Company's antibody collaboration with Sanofi. Moreover, no royalties are payable to Cellectis on any revenue from commercial sales of antibodies from the Company's *VelocImmune* technology.

**14. 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 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 of directors.

In September 2003, Sanofi purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for $45.0 million. See Note 4.

In December 2007, Sanofi 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 entered into an investor agreement, as amended and restated in January 2014, with the Company. Under the terms of the amended and restated investor agreement, Sanofi 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 held by Sanofi from time to time. Under the amended and restated investor agreement, Sanofi has also agreed not to dispose of any shares of the Company's Common Stock beneficially owned by Sanofi from time to time until until the later of (i) December 20, 2020, and (ii) the expiration of the Discovery Agreement with Sanofi, as amended (see Note 4a) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction

involving the Company or the Company's dissolution or liquidation, and certain restrictions have been imposed on the manner of sales thereafter.

Further, pursuant to the amended and restated investor agreement, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of the Company or acquiring more than 30% of the outstanding shares of the Company's Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Company's License and Collaboration Agreement with Sanofi and the Company's ZALTRAP Agreement with Sanofi, each as amended (see Note 4a) and (ii) other specified events. Sanofi has also agreed to vote as recommended by the Company's board of directors, except that it may elect to vote proportionally with the votes cast by all of the Company's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock (taken together), 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.

In addition, upon Sanofi reaching 20% ownership of the Company's then outstanding shares of Class A Stock and Common Stock (taken together), the Company is required to appoint an individual agreed upon by the Company and Sanofi to the Company's board of directors. This individual is required to be independent of the Company, and not to be a current or former officer, director, employee, or paid consultant of Sanofi.

In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of $174.8 million. Sanofi purchased 1,017,401 shares of Common Stock in this offering.

In October 2011, the Company completed a private placement of $400.0 million aggregate principal amount of Notes, which are convertible into shares of the Company's Common Stock. In accordance with accounting guidance for debt with conversion and other options, the Company accounted for the liability and equity components of the Notes separately. The equity component of the Notes was $120.6 million, net of issuance costs. In connection with the offering of the Notes, the Company entered into convertible note hedge and warrant transactions. The Company paid $117.5 million for the convertible note hedge, which was recorded as a reduction to additional paid-in capital. The warrant transactions have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of the Company's Common Stock, at the Company's option. Proceeds received from the warrant transactions totaled $93.8 million and were recorded as additional paid-in capital. The warrants expire at various dates during 2017. See Note 12.

In connection with the Company's January 2014 license and collaboration agreement with Bayer HealthCare for the joint development and commercialization outside the United States of antibody product candidates to PDGFR-beta (see Note 4b), Bayer HealthCare has also agreed to a "standstill" provision, which prohibits Bayer HealthCare and its affiliates from seeking to influence the control of the Company or acquiring more than 20% of the Company's then outstanding shares of Class A Stock and Common Stock (taken together).

**15. Long-Term Incentive Plans**

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated and approved by the Company's shareholders (the "2000 Incentive Plan"), provides for the issuance of up to 41,307,016 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 (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 specified in the 2000 Incentive Plan, except as determined by the Committee in its discretion and subject to the applicable 2000 Incentive Plan documents, the ownership of any unvested Restricted Stock will be transferred to the Company. In such an event, the Company will be obligated to repay the Participant the amount, if any, paid by the Participant for such shares. In addition, if the Company requires a return of the Restricted Stock, 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.

The 2000 Incentive Plan contains provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined in the plan.

As of December 31, 2013, there were 4,378,884 shares available for future grants under the 2000 Incentive Plan.

*a. Stock Options*

Transactions involving stock option awards during 2013 under the 2000 Incentive Plan 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, 2012 | | 20,789,511 | $ 56.03 | | |
| **2013:** | Granted | 3,937,989 | $ 263.77 | | |
| | Forfeited | (141,199) | $ 105.71 | | |
| | Expired | (1,521) | $ 21.46 | | |
| | Exercised | (3,176,512) | $ 27.82 | | |
| | Outstanding at December 31, 2013 | 21,408,268 | $ 98.10 | 7.01 | $ 3,811,441 |
| Vested and expected to vest at December 31, 2013 | | 20,875,388 | $ 95.63 | 6.96 | $ 3,768,120 |
| Exercisable at December 31, 2013 | | 11,322,801 | $ 36.83 | 5.37 | $ 2,709,278 |

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 2013, 2012, and 2011 was $727.5 million, $566.7 million, and $49.2 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

***(Unless otherwise noted, dollars in thousands, except per share data)***

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, 2013, 2012, and 2011. The fair value of each option granted under the 2000 Incentive Plan during 2013, 2012, and 2011 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 |
|---|---|---|---|
| 2013: | | | |
| Exercise price equal to Market Price | 3,937,989 | $ 263.77 | $ 104.90 |
| 2012: | | | |
| Exercise price equal to Market Price | 4,162,653 | $ 167.96 | $ 67.66 |
| 2011: | | | |
| Exercise price equal to Market Price | 4,286,640 | $ 51.96 | $ 23.82 |

For the years ended December 31, 2013, 2012, and 2011, the Company recognized $177.9 million, $67.7 million, and $39.2 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards. As of December 31, 2013, there was $492.5 million of stock-based compensation cost related to outstanding non-performance based stock options, net of estimated forfeitures, which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years.

In addition, there were a total of 770,250 performance-based options issued in 2011 which were outstanding and unvested as of December 31, 2013, and subject to the optionee satisfying certain service conditions, would vest upon achieving certain development milestones for the Company's product candidates. In light of the Company's receipt of regulatory approvals for EYLEA and ZALTRAP, and the status of the Company's development programs at December 31, 2013, the Company estimates that all of the outstanding performance-based options issued in 2011 will vest.

For the years ended December 31, 2013, 2012, and 2011, the Company recognized $8.1 million, $15.3 million, and $11.7 million, respectively, of non-cash stock-based compensation expense related to performance options. As of December 31, 2013 there was $4.2 million of stock-based compensation cost which had not yet been recognized 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 1.0 years.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2013, 2012, and 2011.

| | 2013 | 2012 | 2011 |
|---|---|---|---|
| Expected volatility | 42% | 45% | 48% |
| Expected lives from grant date | 5.3 years | 5.4 years | 6.1 years |
| Expected dividend yield | 0% | 0% | 0% |
| Risk-free interest rate | 1.73% | 0.86% | 1.31% |

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.

***(Unless otherwise noted, dollars in thousands, except per share data)***

*b. Restricted Stock*

A summary of the Company's activity related to Restricted Stock awards for the year ended December 31, 2013 is summarized below:

| **Restricted Stock:** | | **Number of Shares** | | **Weighted-Average Grant Date Fair Value** |
|---|---|---|---|---|
| Outstanding at December 31, 2012 | | 642,499 | $ | 96.68 |
| **2013:** | Granted | 6,080 | $ | 272.70 |
| | Vested | (109,999) | $ | 30.63 |
| | Outstanding at December 31, 2013 | 538,580 | $ | 112.16 |

The Company recognized non-cash stock-based compensation expense from Restricted Stock awards of $14.1 million, $11.1 million, and $5.7 million in 2013, 2012, and 2011, respectively. As of December 31, 2013, there were 538,580 unvested shares of Restricted Stock outstanding and $43.7 million of stock-based compensation cost related to these unvested shares which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 3.8 years.

**16. 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, 2013, there were 44,246 shares available for future grants under the Plan.

**17. 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 recognized $5.7 million, $6.3 million, and $4.1 million of Contribution expense in 2013, 2012, and 2011, respectively. During the first quarter of 2014, 2013, and 2012, the Company contributed 20,603, 38,248, and 63,937 shares, respectively, of Common Stock to the Savings Plan in satisfaction of the 2013, 2012, and 2011 Contribution, respectively.

***(Unless otherwise noted, dollars in thousands, except per share data)***

## 18. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. Income tax expense (benefit) for the years ended December 31, 2013 and 2012 consists of the following:

| | 2013 | 2012 |
|---|---|---|
| Current: | | |
| Federal | $ 201,475 | — |
| State | 23,489 | $ 4,308 |
| Foreign | 433 | — |
| Total current tax expense (benefit) | 225,397 | 4,308 |
| Deferred: | | |
| Federal | 54,910 | (300,319) |
| State | 8,700 | (39,837) |
| Foreign | (9) | — |
| Total deferred tax expense (benefit) | 63,601 | (340,156) |
| Total income tax expense (benefit) | $ 288,998 | $ (335,848) |

In 2013, the Company utilized substantially all of the net operating loss carry-forwards for which deferred tax assets were recorded as of December 31, 2012. The Company also utilized $216.9 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of ISOs, which were credited to additional paid-in capital as realized.

During the year ended December 31, 2012, substantially all income tax expense relating to the Company's pre-tax income was offset by releasing a portion of the Company's valuation allowance. In addition, in the fourth quarter of 2012, the Company recorded a $340.2 million income tax benefit attributable to the release of substantially all of the remaining valuation allowance against the Company's deferred tax assets. The decision to release this valuation allowance was made after the Company determined that it was more likely than not that these deferred tax assets would be realized, and was based on the evaluation and weighting of positive and negative evidence. For example, in the fourth quarter of 2012, the Company achieved a cumulative three-year income position; a significant positive factor that overcame substantive prior negative evidence. In addition, the Company considered forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration.

For the year ended December 31, 2011, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. In 2011, the Company recognized a $1.1 million income tax benefit, consisting of (i) $0.7 million related to tax legislation that allowed the Company to claim a refund for a portion of its unused pre-2006 research tax credits and (ii) $0.4 million in connection with the net tax effect of the change in the Company's unrealized gain (loss) on “available for sale” marketable securities, which was included in other comprehensive income (loss).

***(Unless otherwise noted, dollars in thousands, except per share data)***

A reconciliation of the U.S. statutory income tax rate to the Company's effective income tax rate is as follows:

| | 2013 | 2012 |
|---|---|---|
| U.S. federal statutory tax rate | 35.0 % | 35.0 % |
| State and local income taxes | 3.4 | 5.4 |
| Change in state effective rate | — | 5.4 |
| Other non-deductible and permanent differences | 2.1 | 2.8 |
| Foreign income tax rate differential | 4.9 | — |
| Income tax credits | (4.9) | — |
| Reclassification of net operating losses related to exercises of stock options | — | 9.3 |
| Provision (benefit) attributable to valuation allowances | — | (139.0) |
| Effective income tax rate | 40.5 % | (81.1)% |

In 2013, the difference between the U.S. federal statutory rate of 35% and the Company’s effective tax rate of 40.5% is primarily attributable to increases related to state and local taxes, the non-deductible Branded Prescription Drug Fee, and losses incurred in foreign jurisdictions with rates lower than the federal statutory rate. These increases were partially offset by federal and state income tax credits. In January, 2013, The American Taxpayer Relief Act was enacted, which included a provision to extend the income tax credit for increased research activities retroactively to the tax year ended December 31, 2012, as well as for 2013. As a result of the extension, during 2013, the Company recognized the benefit of both the 2012 and 2013 federal research tax credit, which totaled $34.0 million.

In 2012, the difference between the U.S. federal statutory rate of 35% and the Company’s effective tax rate of (81.1)% was primarily attributable to the benefit of the impact of releasing substantially all of the valuation allowance against deferred tax assets as discussed above, partly offset by increases related to state and local income taxes and non-deductible expenses.

In 2011, the difference between the Company's effective income tax rate and the U.S federal statutory rate of 35% was primarily attributable to an increase in the Company's deferred tax valuation allowance.

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

| | As of December 31, | |
|---|---|---|
| | **2013** | **2012** |
| Deferred tax assets: | | |
| Net operating loss carry-forward | $ 135 | $ 77,119 |
| Fixed assets | 18,902 | 1,380 |
| Deferred revenue | 88,033 | 99,659 |
| Deferred compensation | 109,715 | 53,367 |
| Income tax credit carry-forwards | 9,372 | 71,164 |
| Capitalized research and development costs | 18,942 | 24,437 |
| Other | 34,215 | 23,511 |
| | 279,314 | 350,637 |
| Valuation allowance | (1,830) | (2,486) |
| Total deferred tax assets | 277,484 | 348,151 |
| | | |
| Deferred tax liabilities: | | |
| Accruals | — | (6,824) |
| Convertible senior notes | (929) | (1,171) |
| | (929) | (7,995) |
| | | |
| Net deferred tax assets | $ 276,555 | $ 340,156 |

In 2013, the Company's net deferred tax assets (before valuation allowance) decreased primarily due to utilization of the deferred tax assets relating to net operating loss carry-forward and tax credits to offset tax liabilities associated with the Company's 2013 pre-tax income. These decreases in deferred tax assets were partially offset by increases in the deferred tax assets related to deferred compensation. At December 31, 2013, the Company has retained a valuation allowance against certain state tax credits and other tax-related carry-forwards, as the realizability of these deferred tax assets within the carry-forward period is uncertain.

In 2012, the Company's net deferred tax assets (before valuation allowance) decreased, due primarily to utilization of a portion of the net operating loss carry-forward deferred tax asset to offset potential tax liabilities associated with the Company's 2012 pre-tax income. In addition, as described above, (i) substantially all income tax expense related to the Company's 2012 pre-tax income was offset by releasing a portion of the Company's valuation allowance during 2012 and (ii) in the fourth quarter of 2012, the Company released substantially all of the remaining valuation allowance against the Company's deferred tax assets, resulting in the recognition of a $340.2 million income tax benefit.

As of December 31, 2013, the Company had available for tax purposes unused federal and state net operating loss carry-forwards of $450.4 million which will expire in various years from 2018 to 2032. The tax benefit of these net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, which will be credited to additional paid-in capital when realized. The Internal Revenue Code contains certain provisions that can limit a taxpayer's ability to utilize net operating losses and tax credit carry-forwards in any given year resulting from cumulative changes in ownership interests in excess of 50% over a three-year period. The Company does not believe, however, that any such limitation would have a significant impact on the Company's ability to utilize its net operating losses or income tax credit carry-forwards prior to expiration.

The Company's 2011 federal income tax return is currently under audit by the Internal Revenue Service. In 2011 and early 2012, U.S. federal tax authorities concluded examinations of the Company's 2007, 2008, and 2009 federal income tax returns. The Company's 2009, 2010, and 2011 New York State returns are currently under audit by the state tax authorities. The United States

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and many states generally have statutes of limitation ranging from 3 to 5 years; however, those statutes could be extended due to the Company's net operating loss carry-forward position in a number of the Company's tax jurisdictions. In general, tax authorities have the ability to review income tax returns for loss periods in which the statute of limitation has previously expired to adjust the net operating loss carry-forward or tax credits generated in those years.

The following table summarizes the gross amounts of unrecognized tax benefits, without regard to reduction in tax liabilities or additions to deferred tax assets and liabilities if such unrecognized tax benefits were settled. The amount, if recognized, that would impact the effective tax rate is $23.5 million, $8.4 million, and $4.2 million as of December 31, 2013, 2012, and 2011, respectively.

| | 2013 | 2012 | 2011 |
|---|---|---|---|
| Balance as of January 1 | $ 11,274 | $ 5,596 | $ 12,819 |
| Gross increases related to current year tax positions | 7,620 | 1,873 | 2,192 |
| Gross increases related to prior year tax positions | 8,305 | 3,805 | — |
| Gross decrease due to settlements, recapture, filed returns, and lapse of statutes of limitation | (572) | — | (9,415) |
| Balance as of December 31 | $ 26,627 | $ 11,274 | $ 5,596 |

In 2013 and 2012, the increase in unrecognized tax benefits related primarily to the Company's calculation of certain tax credits. In 2011, the gross decrease in unrecognized tax benefits related to prior year tax positions was primarily due to the conclusion of examinations of the Company's 2007, 2008, and 2009 federal income tax returns by U.S. federal tax authorities. Due to the amounts of the Company's net operating loss carry-forward and tax credit carry-forwards, the Company has not accrued interest or penalties related to these unrecognized tax benefits. The Company believes that it is reasonably possible that its unrecognized tax benefits at December 31, 2013 may decrease by up to $8 million within the next twelve months due to the resolution of federal and New York State audits.

## 19. 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. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

***Proceedings Relating to '287 Patent***

As described more specifically below, the Company is a party to patent infringement litigation involving its European Patent No. 1,360,287 (the "'287 Patent"), which concerns genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (referred to below as "'287 Patent Infringement Litigation"), the Company claims infringement of several of the '287 Patent, and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent.

On September 25, 2013, the Company commenced '287 Patent Infringement Litigation against Kymab Ltd, a company based in the United Kingdom, in the English High Court of Justice, Chancery Division, Patents Court, in London. On December 18, 2013, Kymab filed a defense to the Company's lawsuit and counterclaimed alleging invalidity of the '287 Patent. Kymab previously filed an opposition to the '287 Patent in the European Patent Office in June 2013.

On January 3, 2014, the Company commenced '287 Patent Infringement Litigation against Novo Nordisk A/S, a company based in Denmark, in the English High Court of Justice, Chancery Division, Patents Court, in London.

As the '287 Patent Infringement Litigation proceedings are at an early stage, at this time the Company is not able to predict the outcome or an estimate of gain, if any, related to these proceedings.

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

## 20. Net Income (Loss) Per Share

The Company's basic net income (loss) per share amounts have been computed by dividing net income (loss) by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income (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. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. In 2011, the Company reported a net loss; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net income (loss) per share are as follows:

| | December 31, | | |
|---|---|---|---|
| | **2013** | **2012** | **2011** |
| Net income (loss) - basic | $ 424,362 | $ 750,269 | $ (221,760) |
| Effect of dilutive securities: | | | |
| Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs, net of tax | — | 29,126 | — |
| Net income (loss) - diluted | $ 424,362 | $ 779,395 | $ (221,760) |
| | | | |
| *(Shares in thousands)* | | | |
| Weighted average shares - basic | 97,917 | 94,685 | 90,610 |
| Effect of dilutive securities: | | | |
| Stock options | 10,233 | 14,231 | — |
| Restricted stock | 433 | 715 | — |
| Convertible senior notes | — | 4,761 | — |
| Warrants | 2,707 | 990 | — |
| Dilutive potential shares | 13,373 | 20,697 | — |
| Weighted average shares - diluted | 111,290 | 115,382 | 90,610 |
| | | | |
| Net income (loss) per share - basic | $ 4.33 | $ 7.92 | $ (2.45) |
| Net income (loss) per share - diluted | $ 3.81 | $ 6.75 | $ (2.45) |

Shares which have been excluded from the December 31, 2013, 2012, and 2011 diluted per share amounts because their effect would have been antidilutive, include the following:

| | December 31, | | |
|---|---|---|---|
| *(Shares in thousands)* | **2013** | **2012** | **2011** |
| Stock options | 304 | 325 | 20,942 |
| Restricted stock | — | — | 846 |
| Convertible senior notes | 4,761 | — | 939 |
| Warrants | — | — | 939 |

## 21. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2013, 2012, and 2011 were $16.1 million, $8.6 million, and $6.2 million of accrued capital expenditures, respectively.

**REGENERON PHARMACEUTICALS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
***(Unless otherwise noted, dollars in thousands, except per share data)***

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 13a), the Company recognized a facility lease obligation of $25.0 million during 2013 in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased. The Company did not recognize any such facility lease obligations during 2012 and 2011.

Included in facility lease obligations and property, plant, and equipment at December 31, 2013 was $1.9 million of capitalized and deferred interest for the year ended December 31, 2013, as the related facilities are currently under construction. For the years ended December 31, 2012 and 2011, the Company did not capitalize any interest.

Included in other assets at December 31, 2013 and 2012 were $1.2 million and $3.8 million, respectively, due to the Company in connection with employee exercises of stock options. Such amount was not material at December 31, 2011.

**22. Unaudited Quarterly Results**

Summarized quarterly financial data for the years ended December 31, 2013 and 2012 are set forth in the following tables.

| | First Quarter Ended March 31, 2013 | Second Quarter Ended June 30, 2013 | Third Quarter Ended September 30, 2013 | Fourth Quarter Ended December 31, 2013 |
|---|---|---|---|---|
| | (Unaudited) | | | |
| Revenues [1] | $ 439,664 | $ 457,642 | $ 597,027 | $ 610,412 |
| Net income | $ 98,874 | $ 87,376 | $ 141,306 | $ 96,806 |
| Net income per share - basic | $ 1.02 | $ 0.89 | $ 1.44 | $ 0.98 |
| Net income per share - diluted | $ 0.90 | $ 0.79 | $ 1.25 | $ 0.86 |

| | First Quarter Ended March 31, 2012 | Second Quarter Ended June 30, 2012 | Third Quarter Ended September 30, 2012 | Fourth Quarter Ended December 31, 2012 |
|---|---|---|---|---|
| | (Unaudited) | | | |
| Revenues [2] | $ 231,789 | $ 304,399 | $ 427,687 | $ 414,602 |
| Net income [3] | $ 11,651 | $ 76,743 | $ 191,468 | $ 470,407 |
| Net income per share - basic | $ 0.12 | $ 0.81 | $ 2.02 | $ 4.92 |
| Net income per share - diluted | $ 0.11 | $ 0.70 | $ 1.72 | $ 4.08 |

[1] Revenues in the second quarter of 2013 were reduced by two $10 million up-front payments made to Sanofi to acquire full rights to antibodies to PDGF and antibodies to Ang2 in ophthalmology, as described in Note 4 above. Revenues in the third and fourth quarter of 2013 included recognition of sales and substantive development milestones of $45.0 million and $25.0 million, respectively.

[2] Revenues in the third and fourth quarter of 2012 included substantive development milestones of $65.0 million and $10.0 million, respectively.

[3] Net income for the quarter ended December 31, 2012 included an income tax benefit of $335.8 million, primarily attributable to the release of substantially all of the Company's valuation allowance against its deferred tax assets.

**AMENDMENT NO. 1**
**TO**
**THE REGENERON PHARMACEUTICALS, INC.**
**SECOND AMENDED AND RESTATED 2000 LONG-TERM INCENTIVE PLAN**

On November 15, 2013, the Board of Directors of Regeneron Pharmaceuticals, Inc. (the "Company") approved a 15% reduction in the automatic 2014 annual grant of Nonqualified Stock Option to purchase shares of Company Stock to the Nonemployee Directors pursuant to Section 12 of the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (the "Plan"), from 15,000 shares to 12,750 shares. Capitalized terms used but not defined herein shall have the respective meanings given to such terms in the Plan.

A copy of the Plan was filed by the Company with the Securities and Exchange Commission as Exhibit 99.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-174863) on June 13, 2011.

Exhibit 21.1

**SUBSIDIARIES OF REGENERON PHARMACEUTICALS, INC.**

| **Name of Subsidiary*** | **State or Other Jurisdiction of Incorporation or Organization** |
|---|---|
| Regeneron Ireland | Ireland |
| Regeneron Ireland Holdings | Ireland |
| OSMR Holdings | Bermuda |
| Regeneron International Holdings LLC | Delaware |
| Regeneron UK Limited | United Kingdom |
| Regeneron Genetics Center LLC | Delaware |

_____

* Directly or indirectly wholly owned by Regeneron Pharmaceuticals, Inc.

Exhibit 23.1

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-61132, 333-97375, 333-119257, 333-151941, 333-169569, and 333-174863) and on Form S-3 (No. 333-192091) of Regeneron Pharmaceuticals, Inc., of our report dated February 13, 2014 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 13, 2014

**Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2014

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Robert E. Landry, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2014

/s/ Robert E. Landry
Robert E. Landry
Senior Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

**Certification of Principal Executive Officer and Principal Financial Officer Pursuant to**
**18 U.S.C. Section 1350,**
**As Adopted Pursuant to**
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
February 13, 2014

/s/ Robert E. Landry
Robert E. Landry
Senior Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
February 13, 2014