REGENERON PHARMACEUTICALS INC
Form 10-K
February 12, 2015

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, 2014
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.	a

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	a	Accelerated filer	Non-accelerated filer	Smaller reporting

filer company

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 $27,323,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2014, 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 5, 2015:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,971,868
Common Stock, $.001 par value	100,645,094

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2015 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 86 to 91 of this filing.

Table of Contents

REGENERON PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

Table of Contents

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, including without limitation Regeneron's human genetics initiative; 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®, PRALUENT™ (alirocumab), sarilumab, 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 LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties 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. We commercialize medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis (RA), asthma, and atopic dermatitis.

Our total revenues were $2,819.6 million in 2014, compared to $2,104.7 million in 2013 and $1,378.5 million in 2012. Our net income was $348.1 million, or $3.07 per diluted share, in 2014, compared to $424.4 million, or $3.81 per diluted share, in 2013, and $750.3 million, or $6.75 per diluted share, in 2012. 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). In addition, in July 2014, August 2014, and November 2014, the

U.S. Food and Drug Administration (FDA), European Commission, and Japanese Ministry of Health, Labour and Welfare (MHLW), respectively, approved EYLEA for the treatment of diabetic macular edema (DME). In September 2014, the Japanese MHLW approved EYLEA for myopic choroidal neovascularization (mCNV). In October 2014, the FDA approved EYLEA for the treatment of macular edema following retinal vein occlusion (RVO), which includes macular edema following branch retinal vein occlusion (BRVO). In November 2014, the FDA accepted for priority review the supplemental biologics application (sBLA) for EYLEA for the treatment of diabetic retinopathy in patients with DME, with a target action date of March 30, 2015. We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Regulatory applications have been submitted for EYLEA in Europe and Japan for the treatment of macular edema following BRVO.

Table of Contents

In January 2015, the European Committee for Medicinal Products for Human Use (CHMP) recommended EYLEA for approval for the treatment of visual impairment due to macular edema secondary to CRVO or BRVO.

- 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.
- 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 years and older.

We have 17 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of two Trap-based clinical programs and 15 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune® technology.

Trap-based Clinical Programs

EYLEA

In Phase 3 clinical development for the treatment of wet AMD (Asia) and DME (Asia) in collaboration with Bayer HealthCare. As described below, EYLEA is also being studied in combination with (i) an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) an antibody to angiopoietin-2 (Ang2).

ZALTRAP

In Phase 3 clinical development in metastatic colorectal cancer in the Asia-Pacific region (in collaboration with Sanofi).

Antibody-based Clinical Programs in Collaboration with Sanofi

PRALUENT (alirocumab/REGN727)

Antibody to PCSK9. In Phase 3 clinical development for low-density lipoprotein (LDL) cholesterol reduction and for the prevention of cardiovascular events.

Sarilumab (REGN88)

Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).

Dupilumab (REGN668)

Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis (Phase 3), asthma (Phase 2b), chronic sinusitis with nasal polyps (CSwNP) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).

REGN1033

Antibody to myostatin (GDF8). In Phase 2 clinical development in skeletal muscle disorders.

REGN2222

Antibody against respiratory syncytial virus (RSV). Phase 1 clinical study initiated in the second quarter of 2014. In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015, and will be entitled to receive royalties on any future sales of the product candidate.

Antibody-based Clinical Programs in Collaboration with Bayer HealthCare

REGN2176-3

Combination product comprised of an antibody to PDGFR-beta co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. Phase 1 clinical study for the treatment of wet AMD initiated in the first quarter of 2014.

Table of Contents

Antibody-based Clinical Programs Developing Independently

REGN1908-1909*

Antibody combination in Phase 1/Phase 2 clinical development against allergic disease.

REGN1400

Antibody to ErbB3. In Phase 1 clinical development in oncology.

REGN1154*

Antibody against an undisclosed target. Phase 1 clinical study in Australia completed.

REGN1500*

Antibody to Angptl-3 in Phase 1 clinical development. Studies are ongoing under a partial clinical hold by the FDA that excludes women of childbearing potential.

REGN1193*

Antibody in Phase 1 clinical development against an undisclosed target.

REGN1979

Bispecific antibody against both CD20 and CD3 for use in oncology. Phase 1 clinical study initiated in the third quarter of 2014.

REGN910-3**

Combination product comprised of an antibody to Ang2 co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. Phase 1 clinical study initiated in the fourth quarter of 2014.

REGN2810

Antibody to PD-1. Phase 1 clinical study in oncology initiated in the first quarter of 2015.

Fasinumab (REGN475)*

Antibody to Nerve Growth Factor (NGF). In development for the treatment of pain; currently on partial clinical hold by the FDA limiting duration of trials in osteoarthritis to 16 weeks.

* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate 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 the product candidate.

** We acquired from Sanofi full exclusive rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, which were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive a potential development milestone and royalties on any future sales of the product candidate.

Development of REGN2009, which was an antibody in Phase 1 clinical development against an undisclosed target, was discontinued in the second quarter of 2014. In addition, nesvacumab (REGN910), an antibody to Ang2, and enoticumab (REGN421), an antibody to Delta-like ligand-4 (Dll4), both of which were previously in Phase 1 studies in oncology, are no longer in clinical development.

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. We are executing our long-term objective 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.

In early 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC performs 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 is undertaking both large population-based efforts as well as family-based approaches. RGC leverages laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 50,000 unique samples per year.

Table of Contents

Marketed Products

EYLEA (aflibercept) Injection

We commenced sales of EYLEA for the treatment of wet AMD in November 2011, for the treatment of macular edema following CRVO in September 2012, and for the treatment of DME in July 2014, following receipt of regulatory approval in the United States. In addition, in October 2014, the FDA approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. Bayer HealthCare commenced sales of EYLEA 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 following receipt of regulatory approvals outside the United States. In addition, Bayer HealthCare commenced sales of EYLEA for the treatment of visual impairment due to DME in the third quarter of 2014 following receipt of regulatory approval in the EU. In September 2014, the Japanese MHLW approved EYLEA for mCNV. In the fourth quarter of 2014, Bayer HealthCare submitted a regulatory application in China for EYLEA for the treatment of wet AMD. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO, and DME pending in other countries. In addition, Bayer HealthCare has submitted applications to the European Medicines Agency (EMA) and MHLW seeking marketing authorization in the EU and Japan, respectively, for EYLEA for the treatment of macular edema following BRVO. In January 2015, the CHMP recommended EYLEA for approval for the treatment of visual impairment due to macular edema secondary to CRVO or BRVO.

In September 2014, based on data from the VIVID-DME and VISTA-DME trials, the FDA granted EYLEA Breakthrough Therapy designation for the treatment of diabetic retinopathy in patients with DME. In November 2014, the FDA accepted for priority review the sBLA for EYLEA for the treatment of diabetic retinopathy in patients with DME, with a target action date of March 30, 2015.

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. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from such sales.

Net product sales of EYLEA in the United States were $1,736.4 million in 2014, $1,408.7 million in 2013, and $837.9 million in 2012. Bayer HealthCare records revenue from sales of EYLEA outside the United States. EYLEA net product sales outside of the United States were $1,038.5 million in 2014, $472.1 million in 2013, and $19.0 million in 2012.

ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion

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. 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 $91.4 million in 2014, $70.2 million in 2013, and $31.7 million in 2012. 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.

ARCALYST (rilonacept) Injection for Subcutaneous Use

ARCALYST is available in the United States for the treatment of CAPS in adults and children 12 years 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 were $14.4 million in 2014, $17.1 million in 2013, and $20.2 million in 2012.

Table of Contents

Trap-based Clinical Programs

EYLEA - Ophthalmologic Diseases

Overview

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. CRVO is caused by obstruction of the central retinal vein that leads to a back-up of blood and fluid in the retina. Release of VEGF contributes to increased vascular permeability in the eye and macular edema. In BRVO, a blockage occurs in the blood vessels branching from the main vein draining the retina, resulting in the release of VEGF and consequent retinal edema. For centrally involved DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision. 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.

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.

DME

Phase 3 VISTA-DME and VIVID-DME Trials. We are conducting the VISTA-DME study in the United States. Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. 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.

Based on the results of the Phase 3 VISTA-DME and VIVID-DME trials of EYLEA for the treatment of DME at 52 weeks, we submitted an sBLA for U.S. regulatory approval of EYLEA in DME and in July 2014, the FDA approved EYLEA for the treatment of DME. Bayer HealthCare also submitted an application for marketing approval for the treatment of DME in the EU, and the European Commission approved EYLEA for the treatment of visual impairment due to DME in August 2014. Bayer HealthCare has made regulatory submissions in other markets within Asia Pacific and Latin America.

Both the VIVID-DME and VISTA-DME trials will continue as planned up to 148 weeks.

In September 2014, based on data from the VIVID-DME and VISTA-DME trials, the FDA granted EYLEA Breakthrough Therapy designation for the treatment of diabetic retinopathy in patients with DME. In November 2014, the FDA accepted for priority review the sBLA for EYLEA for the treatment of diabetic retinopathy in patients with DME, with a target action date of March 30, 2015.

Phase 3 VIVID-Japan and VIVID EAST-DME Studies. In the first quarter of 2014, Bayer HealthCare reported positive results from an additional Phase 3 safety study in Japan (VIVID-Japan), which did not change the overall safety profile for EYLEA in DME. The Japanese MHLW approved EYLEA for the treatment of DME in November 2014. 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). This trial is fully enrolled.

Macular Edema Following RVO

Phase 3 VIBRANT Study. Based on the results of the VIBRANT study, a supplemental BLA for U.S. regulatory approval of EYLEA in BRVO was submitted, and the FDA approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO, in October 2014.

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 as described below under "Collaborations with Bayer HealthCare - EYLEA outside the United States." Bayer HealthCare has also submitted applications to the EMA and the Japanese MHLW seeking marketing authorization in the EU and Japan, respectively,

for EYLEA for the treatment of macular edema following BRVO.

Table of Contents

ZALTRAP (ziv-aflibercept) - Oncology

ZALTRAP is a fusion protein that is designed to bind all forms of VEGF-A, VEGF-B, and PlGF, and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for angiogenesis that is needed for tumors to grow. ZALTRAP is in Phase 3 clinical development in metastatic colorectal cancer in the Asia-Pacific region.

Late-Stage Antibody-based Clinical Programs

PRALUENT (alirocumab; PCSK9 Antibody) for LDL cholesterol reduction

Overview

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-C, 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 PRALUENT, that is intended to lower LDL cholesterol.

Clinical Programs

Phase 3 ODYSSEY Program. We and Sanofi initiated the global Phase 3 ODYSSEY program for PRALUENT in the second quarter of 2012. The ODYSSEY program consists of more than 23,500 patients, and includes eleven clinical trials evaluating the effect of PRALUENT, dosed every two weeks, on lowering LDL cholesterol. In addition, the potential of PRALUENT to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial. LDL cholesterol reduction is the primary efficacy endpoint for initial regulatory filings. Additionally, the ODYSSEY program includes two trials of PRALUENT dosed every four weeks, ODYSSEY CHOICE I, which was initiated in the fourth quarter of 2013, and ODYSSEY CHOICE II, which was initiated in the first quarter of 2014. Patients in the ODYSSEY CHOICE I trial receive PRALUENT 300 mg (most in combination with statins) each month and patients in the CHOICE II trial receive PRALUENT 150 mg monotherapy and in combination with non-statin lipid lowering therapy each month. The ODYSSEY studies are being conducted in clinical centers around the world including North America, Western and Eastern Europe, South America, Australia, and Asia.

In 2013, we and Sanofi reported data from the ODYSSEY MONO trial, which evaluated the efficacy and safety of PRALUENT monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. In 2014, we and Sanofi reported detailed positive results from nine additional Phase 3 ODYSSEY studies. All ten studies (ODYSSEY MONO, LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II, and ALTERNATIVE) met their primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at 24 weeks compared to placebo or active comparator. Based on the positive results of these studies, a BLA for U.S. regulatory approval of PRALUENT was submitted, and accepted by the FDA in January 2015. As described further below, an FDA rare pediatric disease priority review voucher was utilized in connection with this BLA submission, as a result of which the submission was accepted by the FDA for priority review; the target date for an FDA decision on the BLA is July 24, 2015. In addition, the EMA recently accepted for review the Marketing Authorization Application (MAA) for PRALUENT.

All patients in the ten trials received PRALUENT in addition to standard-of care lipid-lowering therapy, with the exception of patients in ODYSSEY MONO and some patients in ODYSSEY ALTERNATIVE. The trials included patients with LDL-C not at goal with or without a documented history of cardiovascular disease (CVD), including hypercholesterolemic patients who were at high cardiovascular (CV) risk, had an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH), and/or a history of intolerance to two or more statins, including one at the lowest dose. The trials evaluated two distinct dosing regimens: 150 mg every two weeks or 75 mg every two weeks increasing to 150 mg if needed to reach protocol-specified LDL-C targets. In the trials that used an

individualized approach with 75 mg and 150 mg doses, the majority of patients reached their LDL-C goals while remaining on the 75 mg dose. The 75 mg and the 150 mg doses were delivered with a single, self-administered one-milliliter (mL) injection. A summary of primary efficacy endpoints and most common AEs are as follows:

Table of Contents

Study	Patient group	Primary efficacy endpoint (percent change from baseline in LDL-C at 24 weeks)		Most common AEs[a]
		PRALUENT	Comparator	
LONG TERM PRALUENT (n=1,553) vs. placebo (n=788) 150 mg dose	All patients (high CV risk) (total n=2,341)	61% reduction	1% increase (placebo)[b]	Nasopharyngitis, upper respiratory tract infection, injection site reactions, influenza, diarrhea, urinary tract infection, bronchitis, myalgia, headache, back pain, arthralgia
	- HeFH subgroup (n=416)	56% reduction	7% increase (placebo)[c]	
	- Non-HeFH subgroup (n=1,894)	62% reduction	0.5% reduction (placebo)[d]	
COMBO I PRALUENT (n=209) vs. placebo (n=107) 75 mg/150 mg dose	High CV risk	48% reduction	2% reduction (placebo)[b]	Upper respiratory tract infection, nasopharyngitis, urinary tract infection, dizziness, sinusitis, injection-site reaction
COMBO II PRALUENT (n=479) vs. ezetimibe (n=241) 75 mg/150 mg dose	High CV risk	51% reduction	21% reduction (ezetimibe)[b]	Upper respiratory tract infection, accidental overdose, dizziness, myalgia
OPTIONS I [Baseline statin = atorvastatin 20/40 mg] PRALUENT (n=104) vs. ezetimibe (n=102) or double atorvastatin (n=104) or switch to rosuvastatin[e] (n=45) 75 mg / 150 mg dose	High CV risk	44% - 54% reduction	• 21% - 23% reduction (ezetimibe)[f] • 5% reduction (double statin dose)[b] • 21% reduction (statin switch)[b]	Nasopharyngitis, upper respiratory tract infection, hypertension, back pain
OPTIONS II [Baseline statin = rosuvastatin 10/20 mg] PRALUENT (n=103) vs. ezetimibe (n=101) or double rosuvastatin (n=101) 75 mg / 150 mg dose	High CV risk	36% - 51% reduction	• 11% -14% reduction (ezetimibe)[g] • 16% reduction (statin switch)[g]	Nasopharyngitis, upper respiratory tract infection, hypertension, back pain
ALTERNATIVE PRALUENT (n=126) vs. ezetimibe (n=125)	High CV risk and history of intolerance to two or more statins	45% reduction	15% reduction (ezetimibe)[b]	Myalgia, nasopharyngitis, arthralgia, upper

[Validation arm = atorvastatin 20 mg (n=63)]				respiratory tract infection, headache, fatigue
75 mg / 150 mg dose HIGH FH PRALUENT (n=72) vs. placebo (n=35)	HeFH	46% reduction	7% reduction (placebo)[b]	Nasopharyngitis, injection-site reaction, diarrhea, sinusitis, bronchitis, headache, fatigue
150 mg dose FH I PRALUENT (n=323) vs. placebo (n=163)	HeFH	49% reduction	9% increase (placebo)[b]	
75 mg / 150 mg dose FH II PRALUENT (n=167) vs. placebo (n=82)	HeFH	49% reduction	3% increase (placebo)[b]	Injection site reactions, nasopharyngitis, influenza, headache
75 mg / 150 mg dose				

8

Table of Contents

(continued)

Study	Patient group	Primary efficacy endpoint (percent change from baseline in LDL-C at 24 weeks)		Most common AEs[a]
		PRALUENT	Comparator	
MONO PRALUENT (n=52) vs. ezetimibe (n=51) 75 mg/150 mg dose	Moderate CV risk	48% reduction	16% reduction (ezetimibe)[b]	Nasopharyngitis, influenza, upper respiratory tract infection

a.Occurred in at least 5% of PRALUENT-treated patients. Rare allergic reactions have also been reported.
b.P < 0.0001
c.95% confidence interval of the least squares (LS) mean difference vs. placebo: 57.5% - 69% reduction
d.95% confidence interval of the LS mean difference vs. placebo: 59% - 64% reduction
e.45 patients on atorvastatin 40 mg starting dose switched to rosuvastatin 40 mg
f.For patients on atorvastatin 20 mg starting dose p=0.0004; for patients on atorvastatin 40 mg starting dose p < 0.0001
g.For patients on rosuvastatin 10 mg starting dose p < 0.0001; patients on rosuvastatin 20 mg starting dose did not reach statistical significance

The ODYSSEY ALTERNATIVE trial reassessed statin intolerance, as measured by skeletal muscle AEs, by including a validation arm (atorvastatin 20 mg). Although the study was not designed to demonstrate differences in adverse events between treatment groups, in this trial, there were fewer skeletal muscle AEs in the PRALUENT group compared to patients treated with atorvastatin (32.5% versus 46%, hazard ratio = 0.61; nominal p value = 0.042), and fewer compared to ezetimibe (41%). In addition, there were numerically fewer discontinuations for skeletal muscle AEs in the PRALUENT group (PRALUENT 16%, ezetimibe 20%, atorvastatin 22%). In comparison, the overall rate of discontinuations for skeletal muscle AEs across the Phase 2 and 3 PRALUENT placebo-controlled studies, where the majority of patients were also on statins, was 0.4% for PRALUENT (n=2,476) and 0.5% for placebo (n=1,276).

In January 2015, we and Sanofi announced that the ODYSSEY CHOICE I and ODYSSEY CHOICE II studies met their primary efficacy endpoints. The trials compared the reduction from baseline in LDL-C at 24 weeks with PRALUENT versus placebo in patients with hypercholesterolemia. In these monthly dosing trials, the mean percent reduction in LDL-C from baseline was consistent with that seen in previous Phase 3 trials evaluating PRALUENT in every other week dosing. The most common AEs in the trials (occurring in at least 5% of PRALUENT-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue. Injection site reactions occurred more frequently in the PRALUENT groups compared to placebo. Detailed data will be presented at an upcoming medical conference.

In July 2014, we purchased a priority review voucher from a third party, which had received it through the FDA's Rare Pediatric Disease Priority Review Voucher Program. The priority review voucher entitles the holder to designate a human drug application for priority review. The FDA's goal for reviewing a human drug application with priority review is to take action within 6 months instead of 10 months under standard review. We and Sanofi equally shared the voucher's purchase price of $67.5 million. The FDA rare pediatric disease priority review voucher was utilized in connection with the recent BLA submission for PRALUENT and was the basis for FDA's granting priority review for the application.

Phase 2 Studies. In the first quarter of 2014, the first Phase 2 study with PRALUENT in Japanese patients met its primary endpoint. The results demonstrated that the mean LDL-C percentage reduction from baseline to week 12, the primary efficacy endpoint of the study, was significantly greater in patients randomized to receive one of three doses of PRALUENT administered every other week (Q2W) - 150 mg, 75 mg, and 50 mg, in combination with statin therapy, compared to patients receiving placebo. At week 12, the mean percentage reduction in LDL-C from baseline in patients receiving PRALUENT 50 mg Q2W was 55%, PRALUENT 75 mg Q2W was 62% and PRALUENT 150 mg Q2W was 72%, compared to 3% in the placebo group. TEAEs in this study were reported by 52% of patients in

the PRALUENT 50 mg group, 48% of patients in the 75 mg group, and 64% of patients in the 150 mg group, compared to 32% in the placebo group. The most frequently reported TEAEs were nasopharyngitis, injection site reaction, back pain, cystitis and ligament sprain.

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

Overview

IL-6 is a key cytokine involved in the pathogenesis of RA, causing inflammation and joint destruction. Sarilumab is a fully human monoclonal antibody to IL-6R generated using our VelocImmune technology.

Table of Contents

Rheumatoid Arthritis

Phase 3 SARIL-RA-MOBILITY Trial. 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 methotrexate (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, 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. 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.

In June 2014, efficacy and safety data from the SARIL-RA-MOBILITY study was presented at the annual meeting of The European League Against Rheumatism (EULAR). Additional data from the study was presented at the American College of Rheumatology in November 2014.

Additional Phase 3 Studies. We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-ONE, SARIL-RA-MONARCH, and SARIL-RA-EASY. A Phase 3 trial in Japan, SARIL-RA-KAKEHASI, was also initiated in the fourth quarter of 2014. All these trials, with the exception of SARIL-RA-MONARCH and SARIL-RA-KAKEHASI, are fully enrolled. 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. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-COMPARE, or SARIL-RA-ONE are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab. The SARIL-RA-COMPARE Phase 3 study has been discontinued due to slower than anticipated enrollment; this discontinuation will not impact planned global regulatory filings.

Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. 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.

Dupilumab (REGN668; IL-4R Antibody) for allergic and inflammatory conditions

Overview

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 (allergic) dermatitis, asthma, and chronic sinusitis with nasal polyposis. Dupilumab is a fully human monoclonal antibody generated using our VelocImmune technology that is designed to bind to IL-4R alpha subunit and block signaling from both IL-4 and IL-13.

Atopic Dermatitis

Phase 2a Trial. Data from four Phase 1 and Phase 2 studies of dupilumab in adults with moderate-to-severe atopic dermatitis, a severe chronic form of eczema, were published in the New England Journal of Medicine in July 2014. In the Phase 2a study of 109 patients with moderate-to-severe atopic dermatitis, dupilumab 300 mg administered weekly was associated with rapid and marked sustained improvements in several endpoints such as Eczema Severe Score Index (EASI), Scoring of Atopic Dermatitis (SCORAD), Investigator's Global Assessment Score (IGA), baseline Body Surface Area (BSA), and pruritus. After 12 weeks of treatment, patients receiving dupilumab achieved statistically superior clinical outcomes compared to patients in the placebo group in all measures of disease activity and pruritus. There were notably fewer patients with skin infections associated with dupilumab treatment (5.5%), compared with placebo (24.1%). There were no infection related serious AEs or eczema herpeticum in the dupilumab

group. In the placebo group, three patients with skin infections and four patients with atopic dermatitis exacerbations required hospitalization. The most common TEAEs were nasopharyngitis, headache, and conjunctivitis.

Phase 2b Trial. In July 2014, we and Sanofi announced positive results from a Phase 2b dose-ranging study of dupilumab in adult patients with moderate-to-severe atopic dermatitis. All doses of dupilumab met the primary endpoint of a greater improvement in EASI scores from baseline compared to placebo. In the Phase 2b trial, all five subcutaneous doses of dupilumab showed a dose-dependent improvement in the primary endpoint, the mean percent change in EASI score from baseline to week 16. The improvements in EASI score ranged from a high of 74% for patients in the highest dose group, who received 300 mg weekly, to

Table of Contents

a low of 45% in patients who received the lowest dose of 100 mg monthly, compared to 18% for patients in the placebo group ($p<0.0001$ for all doses). The most common AE in the Phase 2b study was nasopharyngitis, which was balanced across dupilumab treatment groups (18.5% to 23%) compared to placebo (21%). Injection site reactions were more frequent in the dupilumab group (5% to 9.5%) compared to placebo (3%), as was headache (12% to 15%) compared to placebo (8%).

Dupilumab-treated patients showed highly statistically significant and dose-dependent improvements in additional key efficacy measures compared to placebo after 16 weeks of treatment:

- 12% to 33% of dupilumab-treated patients achieved clearing or near-clearing of skin lesions, as measured by an IGA score of 0 or 1, compared to 2% with placebo ($p=0.02$ to $p<0.0001$).
- Dupilumab-treated patients experienced a 16.5% to 47% mean reduction in itching, as measured by the pruritus numerical-rating scale (NRS) score, compared to an increase of 5% in the placebo group ($p=0.0005$ to $p<0.0001$).

This Phase 2b double-blind, placebo-controlled, 16-week, dose-ranging study randomized 380 patients with moderate-to-severe atopic dermatitis, who could not be adequately controlled with topical medication or for whom topical treatment was not advisable. Patients were randomized to receive one of five doses of dupilumab (300 mg weekly, 300 mg every other week, 300 mg monthly, 200 mg every other week, 100 mg monthly) or placebo. Patients in the study had approximately 50% of their skin affected by atopic dermatitis at baseline. In the year preceding enrollment in the study, approximately 35% of patients received an oral corticosteroid and approximately 20% received a systemic non-steroid immunosuppressant for atopic dermatitis. Approximately 60% of patients had another allergic condition, including approximately 40% of patients who had a history of asthma. The follow-up period of the study is ongoing and patients will be followed for 16 weeks after treatment.

Phase 3 Study. In the fourth quarter of 2014, four Phase 3 trials in atopic dermatitis, LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, LIBERTY AD SOLO 2, and LIBERTY AD Open label Extension, were initiated and are currently enrolling patients. LIBERTY AD CHRONOS is a randomized, double-blind, placebo-controlled, multi-national study with the primary objective of demonstrating the efficacy of dupilumab in adults with moderate-to-severe atopic dermatitis when administered concomitantly with topical corticosteroids through 16 weeks. Secondary objectives of the LIBERTY AD CHRONOS study will evaluate the long-term safety and efficacy of dupilumab up to 52 weeks. The LIBERTY AD Phase 3 clinical program will consist of patients with moderate-to-severe atopic dermatitis at sites worldwide.

In November 2014, the FDA granted Breakthrough Therapy designation to dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. This designation is based on positive results from Phase 1 and 2 clinical trials, and the determination that atopic dermatitis is a serious disease and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.

Asthma

Phase 2b Trial. In the fourth quarter of 2014, we and Sanofi announced positive results from the interim analysis of a dose-ranging Phase 2b study of dupilumab in adult patients with uncontrolled moderate-to-severe asthma. In the study, the three highest doses of dupilumab in combination with standard-of-care therapy met the primary endpoint of a statistically significant improvement from baseline in FEV_1 at 12 weeks in patients with high blood eosinophils (greater than or equal to 300 cells/microliter), as compared to placebo in combination with standard-of-care therapy. In addition, two doses of dupilumab (200 mg every other week and 300 mg every other week) showed a statistically significant improvement in mean percent change in FEV_1, as well as a reduction in severe exacerbations, in both the high eosinophils and overall study population. Key results included:

- In the high eosinophils patient group - mean improvements from baseline in FEV_1 (and mean percent change in FEV_1) at 12 weeks, the primary (and a secondary) endpoint of the study were: 390 ml (26%) dupilumab 300 mg every other week (Q2W); 430 ml (26%) dupilumab 200 mg Q2W; 180 ml (10%) placebo. ($p<0.01$)
- In the overall population - mean improvements from baseline in FEV_1 at 12 weeks (and mean percent change in FEV_1) were: 280 ml (18%) dupilumab 300 mg Q2W; 310 ml (18%) dupilumab 200 mg Q2W; 120 ml (6%) placebo. ($p<0.001$)
-

In both the high eosinophils patient group and overall patient group - dupilumab showed a reduction in adjusted annualized rate of severe exacerbations compared to placebo (64% to 75% reduction, $p<0.05$ for high eosinophils group and $p<0.01$ for the overall population)

These results were based on a pre-specified interim analysis, which occurred when all patients had reached week 12 of the 24-week treatment period; the average treatment duration at the time of the analysis was 21.5 weeks. The final analyses on exacerbations and safety will occur at 24 weeks. The most common adverse event was injection site reaction, which was more frequent in the four dupilumab dose groups (13% to 25%) compared to placebo (12%). Other common adverse events in the study included upper respiratory tract infection (10% to 13% dupilumab; 13% placebo), headache (5% to 10% dupilumab; 8% placebo), nasopharyngitis (3% to 10% dupilumab; 6% placebo) and bronchitis (5% to 8% dupilumab; 8% placebo). The incidence of infections was balanced

Table of Contents

across treatment groups (42% to 45% dupilumab; 46% placebo), as was the incidence of serious adverse events (3% to 7% dupilumab; 5% placebo).

The double-blind, placebo-controlled, 24-week, dose-ranging study enrolled 776 adult patients with moderate-to-severe uncontrolled asthma, as defined by the Global Initiative for Asthma 2014 Guidelines. Trial participants were randomized to receive one of four doses of dupilumab (300 mg every other week, 200 mg every other week, 300 mg monthly, 200 mg monthly) or placebo. Approximately 40 percent of patients had high eosinophils across the dose groups. During the treatment period, patients continue their stable medium- or high-dose inhaled corticosteroid and long-acting beta agonist (ICS/LABA) combination product. Patients can administer inhaled rescue medication as needed during the study. A severe exacerbation event during the study is defined as a deterioration of asthma requiring the use of systemic corticosteroids for three or more days, or hospitalization or an emergency room visit. Approximately 77% of randomized patients have a history of atopic disease, which includes atopic dermatitis, allergic conjunctivitis, allergic rhinitis, chronic rhinosinusitis, nasal polyposis, food allergy, and/or hives history.

The 24-week treatment period of the study is ongoing, and patients will be followed for 16 weeks after treatment. Full results of the trial will be presented at an upcoming scientific meeting.

A Phase 3 trial in patients with moderate-to-severe asthma is expected to be initiated during 2015.

Chronic Sinusitis with Nasal Polyps

Phase 2 Study. In the third quarter of 2013, a Phase 2 trial in nasal polyposis was initiated. In September 2014, we and Sanofi announced positive results from the Phase 2 proof-of-concept study of dupilumab in patients with moderate-to-severe CSwNP who did not respond to intranasal corticosteroids. The randomized, double-blind, placebo-controlled study enrolled 60 adult patients with moderate-to-severe CSwNP. Patients in the study received 300 mg of dupilumab or placebo administered once per week subcutaneously for 16 weeks, following an initial loading dose of 600 mg. All patients in the study also received a standard-of-care nasal corticosteroid spray. Patients were eligible for the study if they continued to have severe CSwNP despite standard treatment for at least one month. Fifty percent of patients in the study had received prior surgery for their condition. Asthma was also present in 58 percent of CSwNP patients in the study. The conditions are often co-morbid and symptoms/exacerbations are frequently interdependent.

In the study, dupilumab resulted in a statistically-significant improvement in the size of nasal polyps, as measured by endoscopic Nasal Polyp Score (NPS), the primary endpoint of the study. Statistically significant improvements in all secondary efficacy endpoints were also observed, including objective measures of sinusitis by CT scan, nasal air flow, and patient-reported symptoms (sense of smell, congestion, postnasal drip, runny nose and sleep disturbance). In a pre-specified exploratory analysis, dupilumab-treated patients who also had asthma demonstrated significant improvements in asthma control. The safety profile was consistent with previous studies. The most common AEs with dupilumab were injection site reactions, nasopharyngitis, oropharyngeal pain, epistaxis, headache, and dizziness.

Detailed results of the study will be presented at an upcoming medical conference.

Eosinophilic Esophagitis

Phase 2 Study. A Phase 2 study of dupilumab in eosinophilic esophagitis was initiated in the first quarter of 2015. EoE is a chronic allergic inflammatory disease that is considered a major cause of gastrointestinal illness. Eosinophils are a type of white blood cell that, due to allergens, can accumulate in the esophagus, causing inflammation and tissue injuries that create difficulty swallowing. People with eosinophilic esophagitis may also have allergies, asthma, atopic dermatitis, or chronic respiratory disease.

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.

Table of Contents

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 entered into clinical development in 2014, targets CD20 and CD3.

Regeneron Genetics Center. In early 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. RGC leverages de-identified clinical and molecular data from human volunteers for medically relevant associations in a blinded fashion designed to preserve patients' privacy. 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 is undertaking both large population-based efforts as well as family-based approaches. RGC utilizes laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 50,000 unique samples per year.

Central to the work of RGC is 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. RGC has expanded on its foundational population-based collaboration with Geisinger Health Systems with new partners with other institutions such as Columbia University Medical

Table of Contents

Center, the Clinic for Special Children, Baylor College of Medicine, Sick Kids Foundation, and the National Institutes of Health (NIH).

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. As described further below, in January 2014, we entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta for the treatment of ocular diseases or disorders.

With respect to PDGF antibodies, we made a $10.0 million up-front payment to Sanofi in May 2013, two $5.0 million development milestone payments to Sanofi in 2014, and are obligated to pay up to $30.0 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 $5.0 million development milestone payment and royalties on any future sales.

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. We are obligated to reimburse Sanofi out of our share of ZALTRAP profits, if any, 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, for the foreseeable future, 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 Investigational New Drug application (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.

Under our collaboration agreement, Sanofi will record product sales and cost of sales for commercialized products, and Regeneron has the 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.

Table of Contents

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 Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared (for countries other than Japan). As described above, we are entitled to receive a tiered percentage of EYLEA net sales in Japan.

Since inception of the agreement, we have earned $110.0 million of development milestone payments and $150.0 million of sales milestone payments from Bayer HealthCare. In addition, we may earn a $15.0 million additional sales milestone payment if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve a certain specified level.

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 an 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 license and collaborate on 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. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to us in the first quarter of 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 $15.0 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, continue to pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a $20.0 million opt-in payment to us, pay a $20.0 million development milestone to us upon receipt of the first marketing approval in the European Union or Japan, share profits and losses 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

Table of Contents

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.

Collaboration with Avalanche Biotechnologies, Inc.

In May 2014, we entered into a research collaboration and license agreement with Avalanche Biotechnologies, Inc. to discover, develop, and commercialize novel gene therapy products for the treatment of ophthalmologic diseases. In connection with the agreement, we made a $2.0 million upfront payment and a $6.0 million pre-payment of collaboration research costs, and are obligated to pay potential additional research costs, an aggregate amount of up to $80.0 million per product upon meeting certain potential development and regulatory milestones (for products directed to as many as eight therapeutic targets, or up to an aggregate of $640.0 million), and royalties on any future sales of such products. We also purchased an aggregate of $5.0 million of Avalanche preferred stock. Under the agreement, we collaborate with Avalanche to conduct research for the discovery of novel gene therapy vectors. Subsequent to the filing of an IND with the FDA for a product candidate, we may exercise our right to obtain exclusive worldwide rights to further research, develop, and commercialize such product candidates directed to the applicable therapeutic target. In addition, Avalanche has the option to share in development costs and profits for products directed toward up to two therapeutic targets of its choice.

In July 2014, Avalanche commenced an initial public offering (IPO) of its common stock and thereby triggered our obligation under the research collaboration and license agreement to purchase up to $10.0 million of Avalanche common stock in a concurrent private placement. As part of the concurrent private placement, we purchased from Avalanche at the closing of its IPO shares of Avalanche common stock for an aggregate purchase price of $10.0 million. In addition, at the closing of its IPO, Avalanche preferred stock, including the Avalanche preferred stock held by us, automatically converted on a one-for-one basis into Avalanche common stock.

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of approximately 490,000 square feet of owned research, manufacturing, office, and warehouse space. We currently have approximately 74,000 liters of cell culture capacity at these facilities. These amounts include the impact of an expansion project completed in 2014 which added 20,000 liters of cell culture capacity and 65,000 additional square feet of space. At December 31, 2014, we employed approximately 1,015 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 May 2014, we entered into an agreement to acquire a 400,000 square foot facility in Limerick, Ireland. We are renovating this facility to accommodate and support our growth, primarily in connection with expanding our 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.

Table of Contents

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. We are in the process of significantly expanding the commercialization group to support the potential launch of PRALUENT in 2015, and also to prepare for the potential future launches of sarilumab and dupilumab.

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 several distributors and 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, 2014, 2013, and 2012, we recorded 73%, 76%, and 78%, 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.

Table of Contents

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® (ranibizumab)	Approved	Novartis/Genentech	Wet AMD, DME, macular edema following RVO, choroidal neovascularization secondary to pathologic myopia, diabetic retinopathy in patients with DME, and other eye indications	Worldwide
Avastin® (bevacizumab) (off-label)	Used to treat wet AMD, DME, and macular edema following RVO	Genentech	Wet AMD, DME, and macular edema following RVO	Sold worldwide Being evaluated in trials in the United Kingdom, Canada, Brazil, Germany, and other countries
Conbercept	Approved in China for wet AMD 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	—
RTH258 (ESBA1008), a single chain antibody fragment directed against VEGF-A	In development (non-inferiority Phase 3 trial initiated in 2014 comparing RTH258 (ESBA1008) and EYLEA)	Novartis	Wet AMD	—
Abicipar pegol (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	—
		Pfenex Inc.		—

PF582, a biosimilar to Lucentis®	In development (Phase 1/2)	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."

Table of Contents

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® (bevacizumab)	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 Pharmaceuticals, Inc.	Certain cancers	—

The table above is not exhaustive. For additional information regarding the substantial competition ZALTRAP faces, see 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."

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
PRALUENT (Phase 3) 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
	Eli Lilly	LY3015014	In development (Phase 2)	Antibody against PCSK9
	Alnylam Pharmaceuticals, Inc. (in partnership with The Medicines Company)	ALN-PCS	In development (Phase 1)	RNAi against PCSK9

Table of Contents

(continued)

Regeneron Antibody Program	Competitor	Competitor Product/Product Candidate	Commercial or Development Status	Target
Sarilumab (Phase 3) Target: IL-6R	Roche	Actemra® (Tocilizumab)	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
	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/Phase 2)	Antibody against IL-6
	Roche	SA 237	In development (Phase 1/Phase 3)	Antibody against IL-6R
Dupilumab (Phase 2/Phase 3) 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 3)	Antibody against IL-13
	Novartis	QBX258	In development (Phase 2)	Fixed dose combination of antibodies 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

Table of Contents

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. We hold an ownership interest in a number of issued patents in the United States and 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 2027. 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 2027. 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,

Table of Contents

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 - 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." 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.

Table of Contents

Business Segments

We manage our business as one segment which includes all activities related to the discovery, development, and commercialization of pharmaceutical products for the treatment of serious medical conditions.

Employees

As of December 31, 2014, we had approximately 2,925 full-time employees, of whom approximately 490 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 or Bayer HealthCare are unable to continue to commercialize EYLEA, 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, 2014 and 2013, EYLEA net sales in the United States represented 62% and 67% 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.

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.

We are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA for its currently approved indications in the United States, EU, and other countries where the product is approved. If we fail to maintain regulatory compliance for EYLEA for its currently approved indications, 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.

23

Table of Contents

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 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, health maintenance organizations, pharmacy benefit management companies, 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 and maintaining 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 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. 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 RVO, DME, visual impairment due to mCNV, diabetic retinopathy in patients with DME, 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), in August 2012 for the treatment of DME, and in February 2015 for the treatment of diabetic retinopathy in patients with DME. Lucentis® was also approved by the EMA 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. Competitors are also exploring the development of a biosimilar version of Lucentis® ; in particular, Pfenex Inc. is developing PF582, which is currently in a Phase 1b/2a trial in patients with wet AMD. Other competitive or potentially competitive products include Allergan's Ozurdex® (dexamethasone intravitreal implant) (approved by the FDA in June 2009 for the treatment of macular edema following RVO and in September 2014 for the treatment of DME) and Alimera Sciences' Iluvien® (fluocinolone acetonide intravitreal implant) (approved by the FDA in September 2014 for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids.

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 (RTH258), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated a

non-inferiority Phase 3 trial comparing RTH258 (ESBA1008) and EYLEA in December 2014. Allergan is developing abicipar pegol (an anti-VEGF-A DARPin®) for wet AMD and related conditions and a Phase 2 trial has been completed. 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 targeting both VEGF and Ang2 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 repackaged Avastin®

Table of Contents

in patients with wet AMD presents a significant competitive challenge in this indication. Competitors (including Amgen) are also developing a biosimilar version of Avastin®. 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 repackaged 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 repackaged 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 its approved 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, the value of our company and our business, prospects, operating results, and financial condition will be materially harmed. If we are unable to obtain regulatory approval for our product candidates, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition may be materially harmed. In addition, if we fail to maintain regulatory approval for EYLEA's currently approved indications, 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. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings,

precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

Table of Contents

The FDA may also require us to conduct additional clinical trials after granting approval of a product. Its ability to do so has been enhanced by the Food and Drug Administration Amendments Act of 2007, pursuant to which the FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. Standard review can be accomplished in a ten-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within 6 months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. Even if any of our applications receives a priority review designation (including based on the rare pediatric disease priority review voucher, which we and Sanofi used in connection with the BLA submission for PRALUENT), we may not ultimately be able to obtain approval of our application within a time frame consistent with the FDA's stated review goals or at all, and such designation may not actually lead to a faster development or regulatory review or approval process.

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. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. 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 is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition, 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. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. 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.

Table of Contents

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.

Table of Contents

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 those covered by its currently approved indications. 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 PRALUENT, our PCSK9 antibody for the reduction of LDL cholesterol, as discussed above in Part I, Item 1. "Business - Late-Stage Antibody-based Clinical Programs." As part of this development program, we and Sanofi collect adverse events and report them to the FDA and foreign regulatory authorities. As previously reported, in ten Phase 3 ODYSSEY studies, the most common adverse events were nasopharyngitis and upper respiratory tract infection, which were generally balanced between treatment groups. Injection site reactions were more frequent in the PRALUENT group compared to placebo. Serious adverse events and deaths were generally balanced between treatment groups as were other key adverse events, including musculoskeletal, neurocognitive, and liver-related events. We and Sanofi were advised by the FDA that it had 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. The FDA had requested that we and Sanofi make an assessment of potential neurocognitive adverse events across the global development program for PRALUENT, 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 have reported, based on analyses conducted to date, that neurocognitive adverse events were generally balanced between treatment groups in our Phase 3 studies, if this or another adverse event signal is detected in future analyses or in subsequent data, the possible approval of PRALUENT 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 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, fasinumab was placed on partial 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 expected to continue.

Table of Contents

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, held to be unenforceable, 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. For example, our European Patent No. 1,360,287 has been the subject of opposition proceedings in the European Patent Office, as described in Part I, Item 3. "Legal Proceedings" of this report. 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 patents from challenges by others from time to time in the future. Certain of our U.S. patents 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 patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights.

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 and other proceedings involving our patents. For example, we are currently parties to patent infringement proceedings relating to our European Patent No. 1,360,287 and our U.S. Patent No. 8,502,018, both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part I, Item 3. "Legal Proceedings" of this report. In addition, we are currently parties to patent infringement proceedings initiated by Amgen against us and Sanofi relating to PRALUENT , the antibody to PCSK9 for LDL cholesterol reduction we are jointly developing with Sanofi, as described in Part I, Item 3. "Legal Proceedings" of this report. We are aware of additional patents and pending applications owned by others that claim antibodies to PCSK9 and

Table of Contents

methods of treating hypercholesterolemia with such antibodies. We are also aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R and IL-4R and methods of treating rheumatoid arthritis and uveitis and atopic dermatitis and asthma with such antibodies. In addition to PRALUENT, our late-stage antibody-based pipeline includes sarilumab, an antibody to IL-6R, for the treatment of rheumatoid arthritis and non-infectious uveitis; and dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, chronic sinusitis with nasal polyps, and eosinophilic esophagitis. Although we do not believe that any of our late-stage antibody product candidates 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 our late-stage antibody product candidates, similar to the patent infringement proceedings initiated by Amgen referred to above. 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. None of ARCALYST, ZALTRAP, or EYLEA is a recombinant antibody. 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

Table of Contents

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 will likely 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 have acquired and are renovating a 400,000 square foot facility in Limerick, Ireland 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, the Limerick, Ireland facility remains subject to securing certain permits from the local government, and there is no guarantee that we will be able to obtain the remaining 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.

Table of Contents

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 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 its currently approved indications, 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 other 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.

Many of our products and product candidates are very difficult to manufacture. As our products and product candidates are biologics, they require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us in a timely manner), could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time-consuming, and expensive to transfer our technology to our corporate collaborators or contract manufacturers.

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. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. 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

Table of Contents

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.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payers, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

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 its currently approved indications, our commercialization experience is still relatively limited 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;

Table of Contents

- 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 repackaged 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 existing and new health care laws and regulations currently being implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices.

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. 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.

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- and late-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 (Actemra®) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), 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, 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 submitted a BLA with the FDA and a marketing authorization application with the EMA, 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 in development, including an oral product. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including PRALUENT (if approved). Certain late-stage inhibitors of cholesterylester transfer

protein (CETP), such as Merck's anacetrapib and Eli Lilly's evacetrapib, lower LDL-C and may be launched with supporting data from outcomes trials prior to the completion of our own outcomes trial for PRALUENT. Another oral agent that lowers LDL-C and that may potentially compete with PRALUENT, if approved, is Esperion's ETC-1002. A number of companies are developing antibodies that, if approved, may compete with dupilumab, our IL-4R antibody, if it is approved, including Roche (an antibody against IL-13), Teva (an antibody against IL-5), AstraZeneca (antibodies against IL-5R and IL-13), Novartis (a combination antibody against IL-4 and IL-13), and Amgen (in partnership with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). For muscle-wasting conditions, Pfizer, Eli Lilly, Bristol-Myers Squibb,

Table of Contents

and Atara Biotherapeutics 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 and maintaining 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 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 (such as health maintenance organizations and pharmacy benefit management companies), and other third-party payers, including Medicare and Medicaid, do not adequately 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, or may prefer selected drugs, making drugs that are not covered or preferred by such payers more expensive for patients. Third-party payers may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply and regulatory review of such products. Given cost sensitivities in many health care systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our products, we must, among other things, maintain registration of the products in the National Drug Code registry, maintain our re-labeler license, maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS). There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage) of our current and future products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) 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, repackaged 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 its currently approved indications will likely continue to be too expensive for most patients to afford without health insurance coverage, if third-party payers, including Medicare and Medicaid in the United States, do not continue to provide adequate coverage and reimbursement for EYLEA, our ability to successfully market it would be materially adversely impacted. There is a risk that third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse our current and future 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

Table of Contents

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 and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. 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 several distributors and 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, 2014 and 2013, we recorded 73% and 76%, 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

Table of Contents

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.

As part of the PPACA, the federal government has enacted provisions imposing reporting and disclosure requirements on pharmaceutical manufacturers for any "transfers of value" made or distributed to prescribers and other healthcare providers. These statutory provisions and related regulations (commonly known as the "Sunshine Act") 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 submitted our 2013 Reporting Entity and Payment Aggregate Data in June 2014, as required by the Sunshine Act. 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. In addition, 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. 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 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.

Table of Contents

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;

- our ability to deploy overseas funds in an efficient manner;
- 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.

Table of Contents

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities that involve significant management judgment for uncertain tax positions. The IRS or other domestic or foreign taxing authorities may disagree with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country, the availability of the U.S. research and development tax credit, and changes in tax laws and regulations.

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 the Health Insurance Portability and Accountability Act of 1996 (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. Regeneron is not a HIPAA-covered entity and our clinical research efforts are not directly regulated by HIPAA, so we are not subject to civil penalties under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it, may apply to some or all of the clinical data obtained from our collaborators outside of the U.S. Failure by those collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, 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 statutory or 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.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or

other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Table of Contents

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 PRALUENT, sarilumab, and dupilumab, 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 collaboration 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 REGN2222, and decided not to opt in to the REGN1154, REGN1193, 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.

Table of Contents

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. We cannot assure you that regulatory approvals will be received for EYLEA in additional indications outside the United States or that EYLEA will be successfully commercialized outside the United States. 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 collaborator, 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 its currently approved indications, 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 (or for any other reason lose the services of) 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., President, Regeneron Laboratories and our Chief Scientific Officer; and Neil Stahl, Ph.D., our Executive Vice President, Research and Development. As we continue to commercialize EYLEA and begin to commercialize other products assuming the receipt of required regulatory approvals, 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.

Table of Contents

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 us potentially vulnerable to IT system breakdowns, 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

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 anticipated 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.

Table of Contents

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, British pound sterling, and Australian dollar. 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, 2014, we had $648.7 million in cash and cash equivalents and $711.9 million in marketable securities (including $98.8 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income 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. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of 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, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management companies) affecting the coverage, reimbursement, or use 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 collaborators 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;
- general market conditions;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

Table of Contents

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. As discussed in greater detail under "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" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been increasing its ownership of our Common Stock. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. 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, 2014, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 48.7% 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, 2014. As of December 31, 2014, Sanofi beneficially owned 22,859,144 shares of our Common Stock, representing approximately 22.8% of the shares of Common Stock then outstanding. Under our January 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. In July 2014, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase additional shares of our Common Stock to progressively increase its beneficial ownership in 2014 and 2015 up to the maximum allowed under the "standstill" provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). 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, 2014, holders of Class A Stock held 16.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and 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, 2014:

- our current executive officers and directors beneficially owned 10.7% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2014, and 22.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2014; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 48.7% 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

Table of Contents

December 31, 2014. In addition, these five shareholders plus our Chief Executive Officer held approximately 54.3% 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, 2014.
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. In April 2014, Sanofi notified us that it had reached the 20% ownership threshold and designated Robert A. Ingram as its designee. On April 4, 2014, following recommendation of the Corporate Governance and Compliance Committee, the board of directors elected Mr. Ingram as a director and a member of the Compensation Committee. Mr. Ingram was subsequently elected as a Class I director at our 2014 Annual Shareholder Meeting for a term expiring at the 2016 Annual Shareholder Meeting.
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, 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. As of December 31, 2014, an aggregate principal amount of $169.4 million of the notes and 3,540,095 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.
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.

Table of Contents

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 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.

Table of Contents

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, stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan and our 2014 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plans. 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 706,000 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 323,000 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 commenced during the second half of 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	706,000	June 2024 - June 2029	$2,375,000	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 the second half of 2015.

We own facilities in Rensselaer, New York, consisting of four buildings totaling approximately 490,000 square feet of research, manufacturing, office, and warehouse space, which includes approximately 65,000 square feet of additional manufacturing space for which construction was completed during 2014.

In May 2014, we entered into an agreement to acquire a 400,000 square foot manufacturing facility in Limerick, Ireland for $5.1 million. We are in process of renovating this facility to accommodate and support our growth, primarily in connection with expanding our 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.

Table of Contents

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business, including those described below. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see Part I, Item 1A. "Risk Factors," including the discussion under the headings entitled "Risks Related to Intellectual Property and Market Exclusivity, " "Regulatory and Litigation Risks, " and "Risks Related to Our Common Stock."

Proceedings Relating to '287 Patent and '018 Patent

We are parties to patent infringement litigation involving our European Patent No. 1,360,287 (the '287 Patent) and our U.S. Patent No. 8,502,018 (the '018 Patent), both of which concern 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 and '018 Patent Infringement Litigation, respectively), we claim infringement of several claims of the '287 Patent and the '018 Patent (as applicable), 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 and the '018 Patent (as applicable).

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.

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. On March 27, 2014, Novo Nordisk served a defense to our lawsuit and counterclaimed alleging invalidity of the '287 Patent. Novo Nordisk also intervened in the opposition to the '287 Patent in the European Patent Office on April 3, 2014.

On March 11, 2014, we commenced '287 Patent Infringement Litigation and '018 Patent Infringement Litigation against Merus B.V., a company based in Utrecht, The Netherlands, in the District Court of The Hague and the United States District Court for the Southern District of New York, respectively. On November 21, 2014, the United States District Court for the Southern District of New York issued its Opinion and Order on Claim Construction in the '018 Patent Infringement Litigation, in which it effectively found that Merus did not infringe the '018 Patent and held the '018 Patent invalid. On December 19, 2014, we petitioned the court to enter a final judgment so that we could appeal the court’s ruling.

On March 11, 2014, we commenced '018 Patent Infringement Litigation against Ablexis, LLC, a Delaware corporation with a principal place of business in San Francisco, California, in the United States District Court for the Southern District of New York. On October 31, 2014, we and Ablexis reached a confidential settlement and filed a joint stipulation dismissing the action with prejudice.

Our '287 Patent is also the subject of opposition proceedings in the European Patent Office (EPO) initiated by Kymab and Merus in June 2013, alleging lack of novelty, lack of inventive step, and insufficiency. On September 17, 2014, following an oral hearing held to evaluate the validity of the '287 Patent, the Opposition Division of the EPO revoked the '287 Patent in its entirety on the grounds of lack of inventive step. We filed an appeal with the EPO on September 18, 2014, which had the effect of reinstating the '287 Patent.

Proceedings Relating to PCSK9 Antibody (PRALUENT)

On October 17, 2014 and October 28, 2014, Amgen Inc. filed complaints against Regeneron, Sanofi, Aventisub LLC (subsequently removed and replaced with Sanofi-Aventis U.S. LLC), and Aventis Pharmaceuticals, Inc. in the United States District Court for the District of Delaware seeking an injunction to prevent us and the other defendants from manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) PRALUENT, the antibody to PCSK9 for LDL cholesterol reduction we are jointly developing with Sanofi. On November 11, 2014 and November 17, 2014, Amgen filed complaints against Regeneron, Sanofi, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. in the same court seeking the same relief. Amgen asserts U.S. Patent Nos. 8,563,698, 8,829,165, and 8,859,741 in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 in the second complaint, U.S. Patent No. 8,883,983 in the third complaint, and U.S. Patent No. 8,889,834 in the fourth complaint.

Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. On December 15, 2014, all of the four proceedings were consolidated into a single case.

Table of Contents

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
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
2014		
First Quarter	$352.49	$262.97
Second Quarter	320.00	269.50
Third Quarter	369.31	285.06
Fourth Quarter	437.64	320.06

As of February 5, 2015, there were 245 shareholders of record of our Common Stock and 34 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.

Table of Contents

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 NQ US Benchmark Pharma TR Index, and (ii) Standard & Poor's 500 Stock Index (S&P 500) for the period from December 31, 2009 through December 31, 2014. The comparison assumes that $100 was invested on December 31, 2009 in our Common Stock and in both 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.

	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014
Regeneron	$100.00	$135.77	$229.24	$707.49	$1,138.30	$1,696.65
S&P 500	100.00	112.78	112.78	127.90	165.76	184.64
NQ US Pharma TR Index	100.00	102.60	120.54	137.81	186.98	227.77

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.

Issuance of Common Stock upon Conversion of Notes

In 2014, we settled the conversion of $220.6 million principal amount of our 1.875% convertible senior notes through the payment of $220.6 million in cash (equal to the principal amount of the converted notes) and issuance of 2,017,732 shares of our Common Stock to the holders of the notes surrendered for conversion. We issued and sold the notes in October 2011 in a private placement in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. In connection with this conversion, we exercised a proportionate amount of our convertible note hedges, as a result of which we received from our hedge counterparties 2,017,732 shares of our Common Stock.

Table of Contents

Item 6. Selected Financial Data

The selected financial data set forth below for the years ended December 31, 2014, 2013, and 2012 and as of December 31, 2014 and 2013 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, 2011 and 2010 and as of December 31, 2012, 2011, and 2010 are derived from our audited financial statements not included in this report.

	Year Ended December 31,				
(In thousands, except per share data)	2014	2013	2012	2011	2010
Statement of Operations Data:					
Revenues:					
Net product sales	$1,750,762	$1,425,839	$858,093	$44,686	$25,254
Collaboration revenue	1,036,854	650,400	493,913	369,681	386,725
Technology licensing and other revenue	31,941	28,506	26,471	31,457	47,095
	2,819,557	2,104,745	1,378,477	445,824	459,074
Expenses:					
Research and development	1,271,353	859,947	625,554	529,506	489,252
Selling, general, and administrative	504,755	329,415	210,755	117,261	65,201
Cost of goods sold	129,030	118,048	83,927	4,216	2,093
Cost of collaboration manufacturing	75,988	37,307	528	—	—
	1,981,126	1,344,717	920,764	650,983	556,546
Income (loss) from operations	838,431	760,028	457,713	(205,159)	(97,472)
Other income (expense)	(62,684)	(46,668)	(43,292)	(17,733)	(6,996)
Income (loss) before income taxes	775,747	713,360	414,421	(222,892)	(104,468)
Income tax (expense) benefit [1]	(427,673)	(288,998)	335,848	1,132	—
Net income (loss)	$348,074	$424,362	$750,269	$(221,760)	$(104,468)
Net income (loss) per share - basic	$3.46	$4.33	$7.92	$(2.45)	$(1.26)
Net income (loss) per share - diluted	$3.07	$3.81	$6.75	$(2.45)	$(1.26)

	As of December 31,				
(In thousands)	2014	2013	2012	2011	2010
Balance Sheet Data:					
Unrestricted and restricted cash, cash equivalents, and marketable securities (current and non-current)	$1,360,634	$1,083,875	$587,511	$810,550	$626,939
Total assets	3,871,827	2,951,013	2,080,490	1,323,583	1,089,432
Convertible senior notes (current and non-current)	146,773	320,315	296,518	275,019	—
Facility lease obligations (current and non-current)	312,291	185,197	160,810	160,514	160,030
Capital lease obligations (current and non-current)	—	126	1,309	2,506	2,829
Stockholders' equity	2,542,325	1,952,076	1,245,385	485,732	527,815

(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."

Table of Contents

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. We commercialize medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, RA, asthma, and atopic dermatitis.

Our total revenues were $2,819.6 million in 2014, compared to $2,104.7 million in 2013 and $1,378.5 million in 2012. Our net income was $348.1 million, or $3.07 per diluted share, in 2014, compared to $424.4 million, or $3.81 per diluted share, in 2013, and $750.3 million, or $6.75 per diluted share, in 2012. 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. We commenced sales of EYLEA for the treatment of wet AMD in November 2011, for the treatment of macular edema following CRVO in September 2012, and for the treatment of DME in July 2014, following receipt of regulatory approval in the United States. In addition, in October 2014, the FDA approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. Bayer HealthCare commenced sales of EYLEA 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 following receipt of regulatory approvals outside the United States. In addition, Bayer HealthCare commenced sales of EYLEA for the treatment of visual impairment due to DME in the third quarter of 2014 following receipt of regulatory approval in the EU. In September 2014, the Japanese MHLW approved EYLEA for mCNV. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO, and DME pending in other countries. In addition, Bayer HealthCare has submitted applications to the EMA and MHLW seeking marketing authorization in the EU and Japan, respectively, for EYLEA for the treatment of macular edema following BRVO.

  In September 2014, based on data from the VIVID-DME and VISTA-DME trials, the FDA granted EYLEA Breakthrough Therapy designation for the treatment of diabetic retinopathy in patients with DME. In November 2014, the FDA accepted for priority review the sBLA for EYLEA for the treatment of diabetic retinopathy in patients with DME, with a target action date of March 30, 2015.

  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. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from such sales.

  Net product sales of EYLEA in the United States were $1,736.4 million in 2014, $1,408.7 million in 2013, and $837.9 million in 2012. Bayer HealthCare records revenue from sales of EYLEA outside the United States. EYLEA net product sales outside of the United States were $1,038.5 million in 2014, $472.1 million in 2013, and $19.0 million in 2012.

- ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion. 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. 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 $91.4 million in 2014, $70.2 million in 2013, and $31.7 million in 2012. 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.

- ARCALYST (rilonacept) Injection for Subcutaneous Use. ARCALYST is available in the United States for the treatment of CAPS in adults and children 12 years 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

Table of Contents

other unknown stimuli. Net product sales of ARCALYST were $14.4 million in 2014, $17.1 million in 2013, and $20.2 million in 2012.

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 continued 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 17 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of two Trap-based clinical programs and 15 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune technology.

Trap-based Clinical Programs

EYLEA

In Phase 3 clinical development for the treatment of wet AMD (Asia) and DME (Asia) in collaboration with Bayer HealthCare. As described below, EYLEA is also being studied in combination with (i) an antibody to PDGFR-beta, and (ii) an antibody to Ang2.

ZALTRAP

In Phase 3 clinical development in metastatic colorectal cancer in the Asia-Pacific region (in collaboration with Sanofi).

Antibody-based Clinical Programs in Collaboration with Sanofi

PRALUENT

Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events.

Sarilumab (REGN88)

Antibody to IL-6R. In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).

Dupilumab (REGN668)

Antibody to the IL-4R alpha subunit. In clinical development in atopic dermatitis (Phase 3), asthma (Phase 2b), CSwNP (Phase 2), and EoE (Phase 2).

REGN1033

Antibody to GDF8. In Phase 2 clinical development in skeletal muscle disorders.

REGN2222

Antibody against RSV. Phase 1 clinical study initiated in the second quarter of 2014. In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015, and will be entitled to receive royalties on any future sales of the product candidate.

Antibody-based Clinical Programs in Collaboration with Bayer HealthCare

REGN2176-3

Combination product comprised of an antibody to PDGFR-beta co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. Phase 1 clinical study for the treatment of wet AMD initiated in the first quarter of 2014.

Table of Contents

Antibody-based Clinical Programs Developing Independently

REGN1908-1909*

Antibody combination in Phase 1/Phase 2 clinical development against allergic disease.

REGN1400

Antibody to ErbB3. In Phase 1 clinical development in oncology.

REGN1154*

Antibody against an undisclosed target. Phase 1 clinical study in Australia completed.

REGN1500*

Antibody to Angptl-3 in Phase 1 clinical development. Studies are ongoing under a partial clinical hold by the FDA that excludes women of childbearing potential.

REGN1193*

Antibody in Phase 1 clinical development against an undisclosed target.

REGN1979

Bispecific antibody against both CD20 and CD3 for use in oncology. Phase 1 clinical study initiated in the third quarter of 2014.

REGN910-3**

Combination product comprised of an antibody to Ang2 co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. Phase 1 clinical study initiated in the fourth quarter of 2014.

REGN2810

Antibody to PD-1. Phase 1 clinical study initiated in the first quarter of 2015 in oncology.

Fasinumab (REGN475)*

Antibody to NGF. In development for the treatment of pain; currently on partial clinical hold by the FDA limiting duration of trials in osteoarthritis to 16 weeks.

* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate 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 the product candidate.

** We acquired from Sanofi full exclusive rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, which were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive a potential development milestone and royalties on any future sales of the product candidate.

Development of REGN2009, which was an antibody in Phase 1 clinical development against an undisclosed target, was discontinued in the second quarter of 2014. In addition, nesvacumab (REGN910), an antibody to Ang2, and enoticumab (REGN421), an antibody to Delta-like ligand-4 (Dll4), both of which were previously in Phase 1 studies in oncology, are no longer in clinical development.

Table of Contents

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 2014 and 2015 to date were, and plans for the remainder of 2015 are, as follows:

Trap-based Clinical Programs:

	2014 and 2015 Events to Date	2015 Plans
EYLEA	Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD and macular edema secondary to CRVO, and continued to pursue regulatory applications for marketing approval in additional countries Bayer HealthCare opted-in to the global development and commercialization outside the United States for the treatment of macular edema following BRVO Reported positive two-year results from the Phase 3 VISTA-DME and VIVID-DME studies Bayer HealthCare reported positive results from the VIVID-Japan study Received positive week 52 results from the Phase 3 BRVO VIBRANT study Reported positive results from the Phase 3 SIGHT study in wet AMD in China Bayer HealthCare submitted regulatory applications seeking marketing authorization in the EU and Japan for EYLEA for the treatment of macular edema following BRVO FDA approved EYLEA for the treatment of DME Bayer HealthCare received regulatory approval for EYLEA in the EU for the treatment of visual impairment due to DME Received Breakthrough Therapy Designation from the FDA for the treatment of diabetic retinopathy in patients with DME Bayer HealthCare received regulatory approval for mCNV and DME in Japan FDA approved EYLEA for the treatment of macular edema following RVO (including macular edema following BRVO) FDA accepted for priority review sBLA for diabetic retinopathy in patients with DME Bayer HealthCare submitted application in China for regulatory approval for the treatment of wet AMD CHMP recommended EYLEA for approval for the treatment of macular edema secondary to BRVO	Bayer HealthCare to file for additional ex-US regulatory approvals in DME, macular edema following BRVO, and mCNV Regulatory agency decisions on applications outside the United States for various indications FDA decision on sBLA for diabetic retinopathy in patients with DME

ZALTRAP	
Sanofi received regulatory approval in additional countries for ZALTRAP for patients with mCRC that is resistant to or has progressed following an oxaliplatin-containing regimen	Regulatory agency decisions outside the United States on additional applications for ZALTRAP in the treatment of previously treated mCRC patients

55

Table of Contents

Antibody-based Clinical Programs:

	2014 and 2015 Events to Date	2015 Plans
PRALUENT (PCSK9 Antibody)	Initiated Phase 3 ODYSSEY CHOICE II trial Initiated Phase 3 program in Japan Reported positive top-line results from nine Phase 3 ODYSSEY studies Detailed positive results from four Phase 3 ODYSSEY trials presented at the ESC Congress 2014 BLA accepted for priority review in the United States Regulatory application accepted for review by the EMA Reported positive topline results from ODYSSEY CHOICE I and CHOICE II trials	Continue enrollment of Phase 3 ODYSSEY OUTCOMES trial Report results from additional Phase 3 ODYSSEY trials File for additional regulatory approvals outside the United States FDA decision on U.S. regulatory application
Sarilumab (IL-6R Antibody)	Obtained positive results from Phase 1b RA trial in Japan Positive results from Phase 3 SARIL-RA-MOBILITY trial presented at EULAR and ACR conferences SARIL-RA-COMPARE Phase 3 study discontinued Initiated additional clinical studies, including Phase 3 MONARCH study (head-to-head monotherapy study against adalimumab) Completed patient enrollment in SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-ONE and SARIL-RA-EASY trials	Continue enrollment in Phase 3 SARIL-RA program Complete patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis Report results from additional Phase 3 trials Submit for regulatory approval in the United States
Dupilumab (IL-4R Antibody)	Reported positive Phase 2a data in atopic dermatitis Reported positive Phase 2b data in atopic dermatitis Reported positive Phase 2 data in CSwNP Initiated LIBERTY AD Phase 3 studies in atopic dermatitis Reported positive Phase 2b data in asthma Received Breakthrough Therapy designation from the FDA for the treatment of adults with moderate-to-severe atopic dermatitis	Continue enrollment in LIBERTY AD Phase 3 studies in atopic dermatitis Initiate Phase 3 studies in asthma and CSwNP

	Initiated Phase 2 study in EoE	
REGN1033 (GDF8 Antibody)	Completed patient enrollment in Phase 1 and Phase 2a studies	Report Phase 2a proof-of-concept data
REGN1908-1909 (target not disclosed)	Completed patient enrollment of First in Human study	Continue patient enrollment in Phase 2 study
	Initiated Phase 2 study	
REGN1400 (ErbB3 Antibody)	Completed patient enrollment in Phase 1 study	Determine future development plan
REGN1154 (target not disclosed)		Determine future development plan

Table of Contents

Antibody-based Clinical Programs (continued):

	2014 and 2015 Events to Date	2015 Plans
REGN1500 (Angptl-3 Antibody)	Continued patient enrollment in Phase 1 study	Complete patient enrollment in Phase 1 study
	On partial clinical hold by the FDA	Initiate Phase 2 study
REGN1193 (target not disclosed)	Continued patient enrollment in Phase 1 study	Continue patient enrollment in Phase 1 study
REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA)	Initiated Phase 1 study	Initiate Phase 2 study
	Completed patient enrollment of Phase 1 study	
	Received Breakthrough Therapy designation from the FDA for the treatment of patients with wet AMD	
REGN2222 (RSV)	Initiated Phase 1 study	Complete patient enrollment in Phase 1 study
	Sanofi provided notice that it had elected not to continue co-development effective December 2015	Initiate Phase 3 study
REGN1979 (CD20 and CD3 Antibody)	Initiated Phase 1 study	Continue patient enrollment in Phase 1 study
REGN910-3 (Ang2 Antibody co-formulated with EYLEA)	Initiated Phase 1 study	Continue patient enrollment in Phase 1 study
REGN2810 (PD-1 Antibody)	Initiated Phase 1 study	Continue patient enrollment in Phase 1 study
Fasinumab (NGF Antibody)	On partial clinical hold by the FDA	Re-enter clinical development

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).

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, such as Medicaid and Veterans' Administration (VA), distribution-related fees, prompt pay discounts, and other sales-related deductions. We estimate reductions to product sales based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, estimated payer mix, inventory levels in the distribution channel, shelf life of the product, and other relevant factors. Calculating these provisions involves estimates and

Table of Contents

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 sales-related deductions.

(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
Provision related to current period sales	33.1	77.2	1.6	111.9
Credits/payments	(34.4)	(75.7)	(1.6)	(111.7)
Balance as of December 31, 2014	$3.1	$21.2	$0.5	$24.8

Collaboration Revenue

We earn collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize our technology platforms. These arrangements may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. The terms of these agreements typically include that consideration be provided to us in the form of non-refundable up-front licensing payments, research progress (milestone) payments, payments for development and commercialization activities, and sharing of profits or losses arising from the commercialization of products. In arrangements involving multiple deliverables, we must determine whether each deliverable qualifies as a separate unit of accounting, whether the deliverables have value to the collaborator on a standalone basis, and how the consideration should be allocated to each separate unit of accounting based on the relative selling price of each deliverable. 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. 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.

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.

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, we also recognize, as additional research and development expense in the period when our collaborator incurs development expenses, the portion of the collaborator's development expenses that we are obligated to reimburse.

Under our collaboration agreements, product sales and cost of sales for products which are currently approved are recorded by our collaborators. We share in any profits or losses arising from the commercialization of such products. Our collaborator provides us with our estimated share of the profits or losses from commercialization of such products for the most recent fiscal quarter. Our collaborators' estimates of profits or losses for such quarter are reconciled to actual profits or losses in the subsequent fiscal quarter, and our share of the profit or loss is adjusted accordingly, as necessary.

Table of Contents

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.

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. There were no performance-based options that were unvested as of December 31, 2014.

Table of Contents

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.

Uncertain tax positions are accounted for in accordance with Financial Accounting Standards Board (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

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. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval.

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 2014, 2013, and 2012, cost of goods sold included inventory write-downs and reserves totaling $6.0 million, $9.1 million, and $17.0 million, respectively.

Table of Contents

Results of Operations
Years Ended December 31, 2014 and 2013
Net Income
Net income in 2014 and 2013 consists of the following:

(In millions)	2014	2013
Revenues	$2,819.6	$2,104.7
Operating expenses	(1,981.1)	(1,344.7)
Other income (expense)	(62.7)	(46.6)
Income before income taxes	775.8	713.4
Income tax expense	(427.7)	(289.0)
Net income	$348.1	$424.4

Revenues
Revenues in 2014 and 2013 consist of the following:

(In millions)	2014	2013
Net product sales	$1,750.8	$1,425.8
Collaboration revenue:		
Sanofi	541.3	430.1
Bayer HealthCare	495.6	220.3
Total collaboration revenue	1,036.9	650.4
Technology licensing and other revenue	31.9	28.5
Total revenue	$2,819.6	$2,104.7

Net Product Sales
Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in November 2011, for the treatment of macular edema following CRVO in September 2012, and for the treatment of DME in July 2014. In 2014, EYLEA net product sales increased to $1,736.4 million from $1,408.7 million in 2013 due to higher sales volume. In 2014, ARCALYST net product sales were $14.4 million compared to $17.1 million in 2013.

Table of Contents

Sanofi Collaboration Revenue

Sanofi collaboration revenue, as detailed below, consisted primarily of reimbursement for research and development expenses that we incurred, partly offset by sharing of pre-launch commercialization expenses, in connection with the companies' antibody collaboration. In addition, Sanofi collaboration revenue in 2013 was reduced by two $10.0 million up-front payments 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)	2014	2013
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	$(4.7)	$(30.8)
Reimbursement of Regeneron research and development expenses	4.8	5.6
Other	5.1	9.7
Total ZALTRAP	5.2	(15.5)
Antibody:		
Reimbursement of Regeneron research and development expenses	547.8	453.5
Reimbursement of Regeneron commercialization-related expenses	19.5	1.9
Regeneron's share of losses in connection with commercialization of antibodies	(41.4)	—
Up-front payments to Sanofi for acquisition of rights related to two antibodies	—	(20.0)
Other	10.2	10.2
Total Antibody	536.1	445.6
Total Sanofi collaboration revenue	$541.3	$430.1

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)	2014	2013
Net product sales recorded by Sanofi	$91.4	$70.2
Regeneron's share of collaboration losses	(4.7)	(30.8)

Our share of the loss in 2014 and 2013 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales.

In 2014, Sanofi's reimbursement of our antibody research and development expenses consisted of $160.0 million under our discovery agreement and $387.8 million under our license agreement, compared to $160.0 million and $293.5 million, respectively, in 2013. Under the amended discovery agreement, Sanofi agreed to fund up to $160.0 million per year of our antibody discovery activities. The higher reimbursement of development costs in 2014 compared to 2013 was primarily due to increased development activities for dupilumab, PRALUENT and certain other, earlier-stage antibody product candidates.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize antibody product candidates. These revenues increased in 2014 compared to 2013 primarily due to higher commercialization activities related to PRALUENT.

Table of Contents

During 2014, we and Sanofi began sharing pre-launch commercialization expenses related to PRALUENT and sarilumab in accordance with the companies' antibody collaboration agreement. As a result, we began recording our share of losses in connection with commercialization of antibodies.

In 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. In connection with acquiring from Sanofi full exclusive rights to (i) antibodies targeting the PDGF family of receptors and ligands in opthalmology and all other indications and (ii) antibodies targeting the Ang2 receptor and ligand in ophthalmology, we made two $10.0 million up-front payments to Sanofi.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of December 31, 2014, $54.0 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, primarily consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States, and recognition of sales and substantive development milestones achieved.

Bayer HealthCare Collaboration Revenue	Year Ended December 31,	
(In millions)	2014	2013
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$301.3	$101.5
Sales and substantive development milestones	105.0	70.0
Cost-sharing of Regeneron EYLEA development expenses	23.4	20.9
Other	52.4	27.9
Total EYLEA	482.1	220.3
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	2.9	—
Other	10.6	—
Total PDGFR-beta	13.5	—
Total Bayer HealthCare collaboration revenue	$495.6	$220.3

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in the fourth quarter of 2012, for the treatment of macular edema secondary to CRVO in the fourth quarter of 2013, and for the treatment of visual impairment due to DME in the third quarter of 2014. 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)	2014	2013
Net product sales outside the United States	$1,038.5	$472.1
Regeneron's share of collaboration profit from sales outside the United States	358.3	159.1
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(57.0)	(57.6)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$301.3	$101.5

Table of Contents

Bayer HealthCare records revenue from sales of EYLEA outside the United States. In 2014 and 2013, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

In 2014, we earned, and recorded as revenue, six $15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million, $600 million, $700 million, $800 million, $900 million, and $1 billion, respectively, over a twelve-month period. Additionally, in 2014, we earned a $15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $100 million over a twelve-month period. In 2013, we earned $15.0 million and $10.0 million substantive development milestones 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 milestones 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.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare increased slightly in 2014 compared to 2013. In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us $15.7 million for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any future profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared. This 2014 increase was partly offset by the winding down of various EYLEA development activities.

Other EYLEA revenue increased principally due to higher reimbursement of other Regeneron EYLEA expenses, primarily related to Bayer HealthCare's share of royalties payable to Genentech which commenced in May 2013 pursuant to the license and settlement agreement as described below under "Liquidity and Capital Resources - License and Settlement Agreements with Genentech - EYLEA", in connection with sales of EYLEA outside the United States. Other EYLEA revenue also includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of December 31, 2014, $13.8 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Liquidity and Capital Resources - Collaborations with Bayer HealthCare - PDGFR-beta antibody outside the United States." Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front payment and non-substantive milestones received in the first quarter of 2014. As of December 31, 2014, $19.9 million of the PDGFR-beta up-front and 2014 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 2014 and 2013, we recognized $23.6 million of technology licensing and other revenue related to this agreement. As of December 31, 2014, $81.0 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' Ilaris (canakinumab). In 2014 and 2013, technology licensing and other revenue included $7.9 million and $4.8 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $1,981.1 million in 2014 from $1,344.7 million in 2013. Our average headcount in 2014 increased to 2,629 from 2,153 in 2013, principally in connection with expanding our research and development, and commercialization activities.

Operating expenses in 2014 and 2013 included a total of $307.2 million and $198.4 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 2014 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 2013 compared to recent prior years. As of December 31, 2014, unrecognized Non-cash Compensation Expense related to outstanding stock options was $706.0 million and unvested

Table of Contents

restricted stock awards was $34.5 million. We expect to recognize this Non-cash Compensation Expense over weighted-average periods of 1.9 years and 2.8 years, respectively.

Research and Development Expenses

Research and development expenses increased to $1,271.4 million in 2014 from $859.9 million in 2013. The following table summarizes the major categories of our research and development expenses in 2014 and 2013:

Research and Development Expenses*	Year Ended December 31,		Increase
(In millions)	2014	2013	(Decrease)
Payroll and benefits [1]	$401.6	$290.7	$110.9
Clinical trial expenses	203.0	139.5	63.5
Clinical manufacturing costs [2]	284.8	237.3	47.5
Research and other development costs	137.2	73.1	64.1
Occupancy and other operating costs	116.5	86.4	30.1
Cost-sharing of Bayer HealthCare and Sanofi development expenses [3]	128.3	32.9	95.4
Total research and development expenses	$1,271.4	$859.9	$411.5

* Certain prior year amounts have been reclassified to conform to the current year's presentation.

[1] Includes Non-cash Compensation Expense of $157.1 million in 2014 and $101.9 million in 2013.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes 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, New York manufacturing facility. Also includes Non-cash Compensation Expense of $27.2 million in 2014 and $14.6 million in 2013.

[3] Under our collaborations with Bayer HealthCare and Sanofi, in periods when Bayer HealthCare or Sanofi incurs certain development expenses, we also recognize, as additional research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse. Our collaborators 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 collaborators' 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 additional costs for clinical studies of dupilumab and REGN1033, partly offset by lower EYLEA-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of PRALUENT. Research and other development costs increased primarily due to our 50% share ($33.8 million) of the cost of purchasing an FDA priority review voucher in 2014, as described above under Item 1. "Business - Late-Stage Antibody-based Clinical Programs - PRALUENT (PCSK9 Antibody) for LDL cholesterol reduction" and two $5.0 million development milestone payments we made to Sanofi in 2014 in connection with our acquisition from Sanofi of full exclusive rights to antibodies targeting the PDGF family of receptors in May 2013. 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 PRALUENT and sarilumab development costs, which commenced during the fourth quarter of 2013.

Table of Contents

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 and 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)	2014	2013	(Decrease)
EYLEA	$110.4	$133.3	$(22.9)
PRALUENT	316.4	152.2	164.2
Sarilumab	86.1	51.9	34.2
Dupilumab	169.0	89.0	80.0
Other antibody candidates in clinical development	196.5	120.3	76.2
Other research programs and unallocated costs	393.0	313.2	79.8
Total research and development expenses	$1,271.4	$859.9	$411.5

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: 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.

Table of Contents

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $504.8 million in 2014 from $329.4 million in 2013 primarily due to higher costs associated with the Branded Prescription Drug Fee, higher non-cash Compensation Expense principally for the reason described under "Expenses" above, higher headcount and headcount-related costs, and higher legal costs primarily in connection with patent enforcement. The increase in the Branded Prescription Drug Fee was primarily related to a $40.6 million incremental charge which was recorded in the third quarter of 2014. Under the provisions of the Patient Protection and Affordable Care Act (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. The legislation imposed an annual fee on companies for each calendar year beginning in 2011. This fee is allocated to companies based on their prior year market share of total branded prescription drug sales into these government programs. In July 2014, the Internal Revenue Service (IRS) issued final regulations that provide guidance on the Branded Prescription Drug Fee. The final regulations differ in some respects from the temporary regulations issued by the IRS in 2011, including that a company is liable for the fee based on its branded prescription drug sales in the current year, instead of the liability only being applicable upon the first qualifying branded prescription drug sale of the following fee year under the temporary regulations. As a result of the issuance of these final IRS regulations, we will record an estimate of the fee in the same period in which its qualifying branded prescription drug sales occur. Therefore, in the third quarter of 2014, an incremental charge was recorded to (i) recognize a liability for the estimated fee payable based on 2014 sales through the first nine months of 2014, and (ii) expense the remaining prepaid asset recorded under the previous accounting for the estimated fee payable based on 2013 sales.

Selling, general, and administrative expenses included $120.2 million and $80.0 million of Non-cash Compensation Expense in 2014 and 2013, respectively.

Cost of Goods Sold

Cost of goods sold was $129.0 million in 2014 and $118.0 million in 2013. Cost of goods sold, which primarily consists of royalties, as well as costs in connection with producing EYLEA and ARCALYST commercial supplies, increased principally due to the increase in U.S. EYLEA net sales. In addition, in 2014 and 2013, cost of goods sold included inventory write-downs and reserves totaling $6.0 million and $9.1 million, respectively.

Cost of Collaboration Manufacturing

We manufacture commercial supplies of product for our collaborators. Cost of collaboration manufacturing increased to $76.0 million in 2014 from $37.3 million in 2013 primarily due to royalties payable to Genentech, which commenced in May 2013 pursuant to the license and settlement agreement as described below under "Liquidity and Capital Resources - License and Settlement Agreements with Genentech - EYLEA", in connection with sales of EYLEA outside the United States. Cost of collaboration manufacturing also includes costs in connection with producing commercial supplies for our collaborators.

Other Income and Expense

Total other expenses (net of other income) increased to $62.7 million in 2014 from $46.7 million in 2013. In 2014, we had investment and other income of $8.2 million, compared to investment and other expense of $0.2 million in 2013. In 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 exceeded investment income earned in 2013 on our marketable securities.

Interest expense in 2014 and 2013 includes interest associated with our 1.875% convertible senior notes, including amortization of the note discount and debt issuance costs, and interest associated with our facility lease obligations. Interest expense in 2014 decreased compared to 2013 primarily due to $230.6 million principal amount of our convertible senior notes which were surrendered for conversion during 2014. In addition, in 2014, we recognized a $33.5 million loss in connection with these conversions.

Income Taxes

In 2014, we recorded income tax expense of $427.7 million, based on an effective tax rate of 55.1%. The 2014 effective tax rate was negatively impacted by losses incurred in foreign jurisdictions with rates lower than the U.S.

federal statutory rate and the non-tax deductible Branded Prescription Drug Fee (as described above). In addition, New York State tax legislation enacted in the first quarter of 2014 reduced the New York State income tax rate to zero percent for "qualified manufacturers", including Regeneron, effective in 2014; however, it also resulted in the reduction of our related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in our effective tax rate by less than 1.0% for the year ended December 31, 2014

Table of Contents

In 2013, we recorded income tax expense of $289.0 million, based on an effective tax rate of 40.5%. The 2013 effective tax rate was negatively impacted by 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 in the effective tax rate 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.
We expect our effective tax rate to continue to be negatively impacted by a shift in our geographic mix of profits and losses as we continue our international expansion in 2015. In addition, the federal income tax credit for increased research activities expired on December 31, 2014; as a result, unless tax legislation is enacted to extend or make permanent this federal income tax credit, we expect it will have a negative impact on our effective tax rate.

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

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 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.

Table of Contents

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, and recognition of a substantive milestone in 2012. 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	—	50.0
Reimbursement of Regeneron research and development expenses	5.6	10.7
Other	9.7	13.2
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.

In 2012, we earned a $50.0 million substantive milestone 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 2013.

In 2013, Sanofi's reimbursement of our antibody research and development expenses consisted of $160.0 million under our discovery agreement and $293.5 million 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

69

Table of Contents

2013. The higher reimbursement of development costs in 2013 compared to 2012 was primarily due to increased development activities for PRALUENT 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.

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 milestones, 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 milestones	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. 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. 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 milestones 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 milestones 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 milestones from Bayer HealthCare upon receipt of marketing and pricing approval, respectively, in Japan for EYLEA for the treatment of wet AMD.

Table of Contents

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.

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.

Under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris. 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. 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.

Table of Contents

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]	$290.7	$210.3	$80.4
Clinical trial expenses	139.5	92.3	47.2
Clinical manufacturing costs [2]	237.3	171.7	65.6
Research and other development costs	73.1	58.0	15.1
Occupancy and other operating costs	86.4	71.4	15.0
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

* Certain prior year amounts have been reclassified to conform to the current year's presentation.

[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, New York 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 collaborators' development expenses that we are obligated to reimburse. Our collaborators 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 collaborators' 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 PRALUENT, 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 PRALUENT, 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 PRALUENT and sarilumab development costs, which commenced during the fourth quarter of 2013.

Table of Contents

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
PRALUENT	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

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 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.

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.

Other Income and Expense

Total other expenses (net of other income) 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 investment and other expense of $0.2 million, compared to investment and other 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 exceeded investment income earned in 2013 on our marketable securities.

Interest expense in 2013 and 2012 primarily included 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.

Table of Contents

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.

Liquidity and Capital Resources

Sources and Uses of Cash for the Years Ended December 31, 2014, 2013, and 2012

As of December 31, 2014, we had $1,360.6 million in cash, cash equivalents, and marketable securities compared with $1,083.9 million as of December 31, 2013 and $587.5 million as of December 31, 2012. As described above, in 2014 we earned a total of $105.0 million in sales milestones from Bayer HealthCare (of which $30.0 million was receivable as of the end of the year). 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.

Cash Provided by (Used in) Operating Activities

2014. Net cash provided by operating activities was $743.2 million in 2014. Our net income of $348.1 million in 2014 included the following non-cash expenses: (i) Non-cash Compensation Expense of $307.2 million, (ii) depreciation and amortization of $52.7 million, and (iii) a $33.5 million loss on extinguishment of debt related to the conversion of our convertible senior notes during 2014. In addition, deferred tax assets as of December 31, 2014 increased by $66.6 million, compared to end-of-year 2013, primarily due to an increase in Non-cash Compensation Expense partly offset by the reduction of our deferred tax assets related to the recently enacted New York State tax legislation, which reduced our New York State income tax rate to zero percent effective in 2014.

As of December 31, 2014, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $62.4 million, compared to end-of-year 2013, primarily due to higher amounts receivable from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States, partly offset by lower trade accounts receivable resulting from shortened payment terms to certain of our U.S. EYLEA customers effective January 2014. Inventories increased by $60.9 million, compared to end-of-year 2013, primarily in connection with increased production of EYLEA commercial supplies. Our deferred revenue as of December 31, 2014 increased by $19.1 million, compared to end-of-year 2013, primarily due to (i) the receipt of a $25.5 million upfront payment as well as two $2.5 million non-substantive development milestone payments in 2014 in connection with our PDGFR-beta antibody collaboration agreement with Bayer HealthCare, and (ii) higher deferred revenue in connection with manufacturing commercial supplies of EYLEA for Bayer HealthCare, which is deferred until the product is sold by Bayer HealthCare to third-party customers. These increases were partly offset by 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 $162.2 million as of December 31, 2014, compared to end-of-year 2013, primarily due to (i) higher accruals for sales-related charges (including the impact of the Branded Prescription Drug Fee incremental charge as described above), deductions, and royalties related to EYLEA, (ii) higher payroll-related liabilities primarily driven by an increase in headcount, and (iii) higher expenditures in connection with our expanding research and development

activities.

2013. Net cash provided by operating activities was $583.6 million in 2013. Our net income of $424.4 million in 2013 included Non-cash Compensation Expense of $198.4 million and depreciation and amortization of $41.2 million. 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.

Table of Contents

As of December 31, 2013, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $259.0 million, compared to end-of-year 2012, primarily due to higher trade accounts receivable in connection with EYLEA product sales and a higher receivable balance due from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States. Inventories increased by $48.0 million, compared to end-of-year 2012, primarily in connection with increased production of EYLEA commercial supplies. Our deferred revenue as of 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 as of 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.

2012. 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.

As of December 31, 2012, Sanofi, Bayer HealthCare and trade accounts receivable increased by $588.4 million, compared to end-of-year 2011, primarily due to higher trade accounts receivable in connection with EYLEA product sales. 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 $25.4 million, compared to end-of-year 2011, primarily due to an increase in prepaid royalties resulting from a $60.0 million lump-sum payment we made 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. Our deferred revenue as of 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.

Cash Used in Investing Activities

Net cash used in investing activities was $420.8 million, $355.5 million, and $81.1 million in 2014, 2013, and 2012, respectively. In 2014, 2013, and 2012, purchases of marketable securities exceeded sales or maturities by $87.8 million, $199.1 million, and $31.7 million, respectively. Capital expenditures of $333.0 million, $156.3 million, and $49.3 million in 2014, 2013, and 2012, 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. In addition, capital expenditures in 2014 included costs in connection with the acquisition and renovations of our Limerick, Ireland manufacturing facility.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $209.3 million and $97.6 million in 2014 and 2012, respectively, and net cash provided by financing activities was $77.1 million in 2013. In 2014, $230.6 million principal amount of our 1.875% convertible senior notes was surrendered for conversion, of which $220.6 million was settled prior to December 31, 2014. In accordance with the terms of the notes, we elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted notes, and shares of our Common Stock in respect of any amounts due in excess thereof. Also during 2014, we entered into agreements to reduce the number of warrants held by the warrant holders. Pursuant to the agreements, we paid an aggregate amount of $294.6 million to the warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. Proceeds from issuances of Common Stock, in connection with exercises of employee stock

options, were $126.0 million in 2014 compared to $57.4 million in 2013 and $63.5 million in 2012. In addition, payments for employee tax obligations in connection with stock option exercises were $267.6 million in 2014 compared to $195.1 million in 2013 and $163.3 million in 2012. Cash flows from financing activities also increased by $448.6 million and $216.9 million in 2014 and 2013, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

Table of Contents

Collaborations with Sanofi

ZALTRAP (aflibercept)

As described above under Item 1. "Business - Collaboration Agreements - Collaboration with Sanofi," since September 2003, we and Sanofi have been parties to a global collaboration for the development and commercialization 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. We are obligated to reimburse Sanofi out of our share of ZALTRAP profits, if any, for 50% of the development expenses that it funded, as well as 50% of the $25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits, or at a faster rate at our option. 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 $461 million as of December 31, 2014.

Refer to "Results of Operations" above for Sanofi collaboration revenue recognized in connection with our ZALTRAP collaboration.

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

As described above under Item 1. "Business - Collaboration Agreements - Collaboration with Sanofi," since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. Under the amended discovery agreement, Sanofi agreed to fund up to $160 million per year of our antibody discovery 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 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. Consequently, commencing in 2013, we recognized as additional research and development expense $109.7 million and $17.6 million in 2014 and 2013, respectively, of antibody development expenses that we were obligated to reimburse to Sanofi related to PRALUENT and sarilumab. 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 $1,304 million as of December 31, 2014. 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. To date, we have exercised our right to co-promote PRALUENT in the United States. 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). Effective in the second and fourth quarters of 2014, we and Sanofi began sharing pre-launch commercialization expenses related to PRALUENT and sarilumab, respectively, which resulted in us recording our share of the loss in connection with commercialization of antibodies of $41.4 million in 2014. In addition to profit sharing, we are entitled to

Table of Contents

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. Additionally, during 2014, Sanofi agreed to fund up to $17.5 million of agreed-upon 2014 and 2015 costs incurred by us in connection with expanding manufacturing capacity at our Rensselaer, New York facility.

In 2014, in connection with the antibody collaboration, we purchased an FDA priority review voucher from a third party for $67.5 million. We and Sanofi equally shared the priority review voucher's purchase price. We subsequently transferred the voucher to Sanofi, which used the priority review voucher in connection with the BLA submission to the FDA for PRALUENT.

With respect to our antibody collaboration with Sanofi, $110.6 million was included in accounts receivable as of December 31, 2014. Refer to "Results of Operations" above for Sanofi collaboration revenue recognized in connection with our antibody collaboration.

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.

Collaborations with Bayer HealthCare

EYLEA outside the United States

As described above under Item 1. "Business - Collaboration Agreements - Collaboration with Bayer HealthCare," 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.

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 Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales. 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 $263 million as of December 31, 2014. 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.

Since inception of the agreement, we have earned $110.0 million of development milestones and $150.0 million of sales milestones from Bayer HealthCare. In addition, we may earn an additional $15.0 million sales milestone if twelve-month sales of specific commercial supplies of EYLEA outside the United States achieve certain specified levels.

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. Refer to "Results of Operations" above for Bayer HealthCare collaboration revenue recognized in connection with our EYLEA collaboration. We also funded $18.6 million, $15.3 million, and $21.9 million of Bayer HealthCare's EYLEA development expenses in 2014, 2013, and 2012, respectively. As of December 31, 2014, $155.8 million was receivable from Bayer HealthCare in connection with the companies' EYLEA collaboration.

Table of Contents

In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO will also be shared (for countries other than Japan). As described above, we are entitled to receive a tiered percentage of EYLEA net sales in Japan.

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 an 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 license and collaborate on 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. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to us in the first quarter of 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 $15.0 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, continue to 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 and losses 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.

Table of Contents

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' Ilaris, 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. Ilaris 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

In December 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 cumulative relevant sales of EYLEA over $3 billion.

In May 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 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 EYLEA sales outside the United States to worldwide EYLEA sales and determined consistent with the license and collaboration agreement.

Also in May 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 706,000 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. Monthly lease payments on Buildings A and B commenced in 2009 and in 2011 on Building C. 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 323,000 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 commenced during the second half of 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 the second half of 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.

Table of Contents

Certain leased premises are accounted for as operating leases. However, for Buildings A, B, C, D, and E (collectively, the Buildings) that we are leasing, we are deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of FASB authoritative guidance. 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. In addition, we recognize, 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. As of December 31, 2014 and 2013, the Buildings' facility lease obligation balance was $312.3 million and $185.2 million, respectively.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $333.0 million in 2014, $156.3 million in 2013, and $49.3 million in 2012.

In May 2014, we entered into an agreement to acquire a 400,000 square foot facility in Limerick, Ireland for $5.1 million. We are renovating 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 $650 million to $800 million in 2015 primarily in connection with renovating our new Limerick, Ireland facility, tenant improvements primarily related to the two new buildings under construction at our leased Tarrytown, New York facilities, expanding, and renovating a portion of our manufacturing facilities at our Rensselaer, New York facility, and purchases of equipment.

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 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.

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 will become exercisable (and, if not exercised, will expire) at various dates during 2017.

During 2014, $230.6 million principal amount of our $400.0 million aggregate principal amount of our convertible senior notes was surrendered for conversion. In accordance with the terms of the notes, we elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted notes, and shares of our Common Stock in

Table of Contents

respect of any amounts due in excess thereof. In 2014, as a result of the settlement of $220.6 million of the notes surrendered for conversion, we exercised a proportionate amount of our convertible note hedges, for which we received 2,017,732 shares of Common Stock, which was equivalent to the number of shares we were required to issue to settle the non-cash portion of the related note conversions. The shares received were recorded as Treasury Stock. Settlement on the remaining notes surrendered in 2014 is anticipated during the first quarter of 2015.

During the first quarter of 2015, we received notification that an additional $6.7 million principal amount of notes were surrendered for conversion, and settlement is anticipated during the first quarter of 2015. We elected to settle these conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the notes). In connection with these note conversions, we exercised a proportionate amount of its convertible note hedges, for which we expect to receive shares of Common Stock equivalent to the number of shares we will be required to issue to settle the non-cash portion of the related note conversions.

During 2014, we entered into agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, we paid an aggregate amount of $294.6 million to the warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants from 4,760,840 to 3,540,095 (subject to adjustment from time to time as provided in the applicable warrant agreements).

Additionally in November 2014, we entered into an amendment agreement with a warrant holder whereby the parties have agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 493,229, for an aggregate amount payable by us not to exceed $148.5 million. The reduction in the number of warrants will be determined based on the number of warrants with respect to which the warrant holder has closed out its hedge position, provided that the warrant holder does not effect any purchases at a price per share exceeding $397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. We are obligated to settle any payments due under the amendment agreement in February 2015. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2014, we recorded an accrued liability of $59.8 million with respect to the expected payment to reduce the number of warrants held by such warrant holder by 202,560 as of December 31, 2014. During the first quarter of 2015, the warrant holder closed out additional portions of its hedge position, and, as a result, we expect to pay an additional $62.0 million to further reduce the number of warrants held by such warrant holder by 206,480.

Funding Requirements

We expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, costs related to the preparation for potential commercialization of our late-stage antibody product candidates, 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 antibodies collaboration 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.

Table of Contents

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2014. 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]	$175.7	$13.2	$162.5	—	—
Operating leases [2]	108.6	10.8	19.8	$19.7	$58.3
Purchase and other obligations [3]	771.1	659.8	103.6	7.7	—
Facility lease obligations [4]	286.6	18.1	37.4	39.0	192.1
Total contractual obligations	$1,342.0	$701.9	$323.3	$66.4	$250.4

(1) Consists of $169.4 million remaining 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 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. See Note 12 to our Consolidated Financial Statements.

(2) Excludes future contingent costs for utilities, real estate taxes, and operating expenses. In 2014, these costs were $13.6 million. See Note 13(a) to our Consolidated Financial Statements.

(3) Purchase and other obligations primarily relate to (i) a $59.8 million payment expected to be made in February 2015 to a warrant holder (see Note 12 to our Consolidated Financial Statements), (ii) research and development commitments, including those related to clinical trials, (iii) capital expenditures for equipment acquisitions, and (iv) 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 the second half of 2015, and will be based on several factors, including the landlord's costs of construction and tenant allowances. See Note 13(a) to our Consolidated Financial Statements.

Liabilities for unrecognized tax benefits, totaling $57.6 million at December 31, 2014, are not included in the table of contractual obligations above as, due to their nature, there is a high degree of uncertainty regarding the period of potential future cash settlement with taxing authorities. See Note 18 to our Consolidated Financial Statements.

We enter into research collaboration and licensing agreements that may require us to pay amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant. Additionally, if required by the agreement, we may be required to make royalty payments calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted. Because of these factors, such payments are not included in the table of contractual obligations above. See Note 4 and Note 13 to our Consolidated Financial Statements.

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 is 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, 2014, our contingent reimbursement obligation to Sanofi for ZALTRAP was approximately $461 million, while our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $263 million. Therefore, we expect that, for the foreseeable future, 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.

Table of Contents

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, 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 market share of total branded prescription drug sales into these government programs.

As described above, in 2014, 2013, and 2012, we made cash payments of $267.6 million, $195.1 million, and $163.3 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 be substantial.

As described under "Convertible Senior Notes" above, in 2014, a portion of our 1.875% convertible senior notes was surrendered for conversion. In future periods, additional notes may be surrendered for conversion. We may also from time to time seek to repurchase or retire our outstanding convertible senior notes, or other outstanding securities, through cash purchases or exchanges for other securities, in open market purchases, privately negotiated transactions, or otherwise.

Due to the amounts of our tax credit carry-forwards available for tax purposes, which totaled approximately $143 million at December 31, 2014, and potential excess tax benefits in connection with stock option exercises, we expect our cash income tax payments for 2015 to be significantly less than the income tax expense recorded in our financial statements in 2015, which is based on an effective tax rate.

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 are eligible to receive an additional $15.0 million sales milestone payment if twelve-month sales of specific commercial supplies of EYLEA outside the United States exceed $200 million.

In connection with our PDGFR-beta antibody agreement with Bayer HealthCare, we are eligible to receive up to $15.0 million in future development milestone payments from Bayer HealthCare (representing 50% of the development milestone payments potentially due to Sanofi as described above), although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration. Furthermore, if Bayer HealthCare exercises their right to opt-in to the collaboration, they will be obligated to pay a $20.0 million opt-in payment to us, and pay a $20.0 million development milestone to us upon receipt of the first marketing approval in the EU or Japan.

Other than letters of credits totaling $7.3 million as of December 31, 2014, we have no off-balance sheet arrangements. As of December 31, 2014, 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.

Table of Contents

Future Impact of Recently Issued Accounting Standards

In May 2014, the FASB issued a new standard related to revenue recognition, Revenue from Contracts with Customers, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. The new standard will be effective for interim and annual reporting periods beginning after December 15, 2016, and early adoption is not permitted. The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. We have not yet determined our method of transition and are evaluating the impact that this guidance will have on our financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our 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, and municipal bonds. We do not believe we are materially exposed to changes in interest rates. We do not currently 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 $6.7 million and $6.8 million decrease in the fair value of our investment portfolio as of December 31, 2014 and 2013, respectively.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. During 2014 and 2012, we recorded no charges for other-than-temporary impairments of our marketable securities. During 2013, we recorded an other-than-temporary impairment charge of $2.9 million related to our investment in an equity security.

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 several distributors and 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 2014, 2013, and 2012, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. As of December 31, 2014 and 2013, one individual customer accounted for 70% and 75%, 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 collaborators 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-43 of this report. The supplementary financial information required by this Item is included at page F-43 of this report.

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

None.

84

Table of Contents

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, 2014 using the framework in Internal Control - Integrated Framework (2013) 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, 2014. The effectiveness of our internal control over financial reporting as of December 31, 2014 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, 2014 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.

Table of Contents

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 2015 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 & Media" 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 2015 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 2015 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 2015 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 2015 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, relating to 1.875% Convertible Senior Notes due October 1, 2016, between Regeneron Pharmaceuticals, Inc. (the "Registrant") 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)	– Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.

Table of Contents

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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.
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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.
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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.
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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.
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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.
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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (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 under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (revised)
10.1.10 +	(gg)	–	Amendment No. 1 to the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan.
10.2 +	(hh)	–	Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.2.1 +	(ii)	–	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.2.2 +	(ii)	–	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.2.3 +	(ii)	–	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 under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.2.4 +	(ii)	–	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.3 +	(p)	–	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.

10.4* +	(d)	–	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.5 +	(ee)	–	Offer Letter for Robert E. Landry effective September 9, 2013.
10.6 +	(p)	–	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
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.

Table of Contents

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*		–	Restated Amendment Agreement, dated December 30, 2014 and entered into effective as of May 7, 2012, by and between Bayer HealthCare LLC and the Registrant.
10.11	(kk)	–	License and Collaboration Agreement, dated as of January 10, 2014, by and between Bayer HealthCare LLC and the Registrant.
10.12	(j)	–	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant.
10.12.1*	(l)	–	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.
10.12.2	(o)	–	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.12.3	(q)	–	Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.12.4	(s)	–	Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009.
10.12.5	(t)	–	Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10.12.6	(w)	–	Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010.
10.12.7	(y)	–	Seventh Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of December 22, 2010.
10.12.8	(bb)	–	Eighth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 1, 2011.
10.12.9	(bb)	–	Ninth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 30, 2011.
10.12.10	(ff)	–	Eleventh Amendment to Lease by and between BMR-Landmark at Eastview LLC and the Registrant, dated April 3, 2013.
10.12.11	(ff)	–	Twelfth Amendment to Lease by and between BMR-Landmark at Eastview LLC and the Registrant, dated May 31, 2013.
10.12.12	(ff)	–	Thirteenth Amendment to Lease by and between BMR-Landmark at Eastview LLC and the Registrant, dated May 31, 2013.
10.13	(ff)	–	Mt. Pleasant Lease by and between BMR-Landmark at Eastview LLC and the Registrant, dated April 3, 2013.
10.14*	(k)	–	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant.
10.14.1*	(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.
10.15*	(v)	–	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.16*	(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.
10.16.1*	(ff)	–	First Amendment to Amended and Restated License and Collaboration Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 1, 2013.
10.17	(jj)	–	Amended and Restated Investor Agreement, dated as of January 11, 2014, by and among Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant.

Table of Contents

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 the Registrant and Goldman, Sachs & Co.
10.20	(aa)	–	Master Terms and Conditions for Convertible Note Hedging Transactions, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Goldman, Sachs & Co. and the Registrant.
10.21	(aa)	–	Master Terms and Conditions for Base Warrants, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Goldman, Sachs & Co. and the Registrant.
10.21.1	(ll)	–	Amendment, dated as of May 15, 2014, to the Master Terms and Conditions for Warrants, between Goldman, Sachs & Co. and the Registrant.
10.21.2		–	Second Amendment, dated as of November 25, 2014, to the Master Terms and Conditions for Warrants, between Goldman, Sachs & Co. and the Registrant.
10.22	(aa)	–	Master Terms and Conditions for Convertible Note Hedging Transactions, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Citibank, N.A. and the Registrant.
10.23	(aa)	–	Master Terms and Conditions for Base Warrants, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Citibank, N.A. and the Registrant.
10.23.1	(ll)	–	Amendment, dated as of May 13, 2014, to the Master Terms and Conditions for Warrants, between Citibank, N.A. and the Registrant.
10.24	(aa)	–	Master Terms and Conditions for Convertible Note Hedging Transactions, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Credit Suisse International and the Registrant.
10.25	(aa)	–	Master Terms and Conditions for Base Warrants, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Credit Suisse International and the Registrant.
10.25.1	(ll)	–	Amendment, dated as of May 14, 2014, to the Master Terms and Conditions for Warrants, between Credit Suisse Capital LLC (as assignee of Credit Suisse International) and the Registrant.
10.25.2		–	Second Amendment, dated as of November 18, 2014, to the Master Terms and Conditions for Warrants, between Credit Suisse Capital LLC (as assignee of Credit Suisse International) and the Registrant.
10.25.3		–	Third Amendment, dated as of November 24, 2014, to the Master Terms and Conditions for Warrants, between Credit Suisse Capital LLC (as assignee of Credit Suisse International) and the Registrant.
10.26	(aa)	–	Master Terms and Conditions for Convertible Note Hedging Transactions, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Morgan Stanley & Co. International plc and the Registrant.
10.27	(aa)	–	Master Terms and Conditions for Base Warrants, dated as of October 18, 2011, as supplemented by a confirmation dated October 18, 2011, between Morgan Stanley & Co. International plc and the Registrant.
10.27.1	(ll)	–	Amendment, dated as of May 16, 2014, to the Master Terms and Conditions for Warrants, between Morgan Stanley & Co. International plc and the Registrant.
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 the Registrant, effective May 17, 2013.
10.28.2*	(ff)	–	

			Non-Exclusive License and Settlement Agreement by and between Genentech, Inc., the Registrant, 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, the Registrant, Regeneron UK Ltd and Genentech Inc.
10.29*	(ff)	–	Letter Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 2, 2013.
21.1		–	Subsidiaries of the Registrant.
23.1		–	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1		–	Power of Attorney (included on the signature page of this Annual Report on Form 10-K).
31.1		–	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

Table of Contents

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 the Registrant, filed November 13, 2007.
(b)	Incorporated by reference from the Form 8-K for the Registrant, filed December 16, 2005.
(c)	Incorporated by reference from the Form 8-K for the Registrant, filed December 13, 2004.
(d)	Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2004, filed March 11, 2005.
(f)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2003, filed November 12, 2003.
(g)	Incorporated by reference from the Form 8-K for the Registrant, filed January 11, 2005.
(h)	Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2005, filed February 28, 2006.
(i)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2006, filed November 6, 2006.
(j)	Incorporated by reference from the Form 8-K for the Registrant, filed December 22, 2006.
(k)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2007, filed May 4, 2007.
(l)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2007, filed November 7, 2007.
(m)	Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2007, filed February 27, 2008.
(n)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2008, filed August 1, 2008.
(o)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2008, filed November 5, 2008.
(p)	Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2008, filed February 26, 2009.
(q)	Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.
(r)	Incorporated by