REGENERON PHARMACEUTICALS INC
Form 10-K
February 11, 2016

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, 2015
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 $50,626,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2015, 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 4, 2016:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,913,776
Common Stock, $.001 par value	102,874,369

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2016 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 91 to 97 of this filing.

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REGENERON PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
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PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation sarilumab, dupilumab, fasinumab, and REGN2222; the likelihood and timing of achieving any of our anticipated clinical development milestones; 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 Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA® (aflibercept) Injection and Praluent), 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, high low-density lipoprotein (LDL) cholesterol, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis (RA), asthma, atopic dermatitis, pain, and infectious diseases.

Our significant 2015 business highlights include:

- EYLEA (aflibercept) Injection, which is approved by the U.S. Food and Drug Administration (FDA) for use in retinal indications, delivered net sales growth of 54% over 2014, and is now the market-leading, branded anti-VEGF therapy in the United States.
- We, along with our partner Sanofi, received regulatory approval in the United States and Europe for Praluent (alirocumab) Injection for the treatment of uncontrolled LDL-cholesterol in certain patients. Praluent has been launched in the United States and certain European countries.
- We reported positive data from three Phase 3 studies of sarilumab in rheumatoid arthritis and submitted a regulatory application to the FDA.
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We reported positive, pivotal, Phase 2b data for dupilumab in the asthma indication and completed enrollment of three Phase 3 studies of dupilumab in atopic dermatitis.

- Two of our antibodies advanced to Phase 3 studies: REGN 2222 for the prevention of Respiratory Syncytial Virus (RSV) infection in infants; and fasinumab, an antibody against nerve growth factor (NGF), for osteoarthritis pain.
- We entered into significant new research and development collaborations: a collaboration with Mitsubishi Tanabe Pharma Corporation for fasinumab in certain Asian countries and a broad immuno-oncology collaboration with Sanofi.
- Our initiatives in genomics also advanced, enabling us to sequence exomes at the rate of 100,000 per year.

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- From a company growth perspective, we hired our 4,000th employee, expanded into two new buildings on our Tarrytown, New York campus, continued to expand our bulk drug product manufacturing operations in Rensselaer, New York, and continued building out and hiring people for our new Limerick, Ireland commercial manufacturing facility.
- We were named one of the two top employers in the global biopharmaceutical industry by Science, for the fifth consecutive year.

Our total revenues were $4,103.7 million in 2015, compared to $2,819.6 million in 2014 and $2,104.7 million in 2013. Our net income was $636.1 million, or $5.52 per diluted share, in 2015, compared to $338.1 million, or $2.98 per diluted share, in 2014, and $413.7 million, or $3.72 per diluted share, in 2013. 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, 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), diabetic macular edema (DME), macular edema following retinal vein occlusion (RVO), which includes macular edema following central retinal vein occlusion (CRVO) and macular edema following branch retinal vein occlusion (BRVO). EYLEA is also available in Japan and the EU for the treatment of myopic choroidal neovascularization (mCNV) and in the United States for the treatment of diabetic retinopathy in patients with DME. Bayer HealthCare has additional regulatory applications for EYLEA for various indications pending in other countries. We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.
- Praluent (alirocumab) Injection, which is available in the United States where it is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (heterozygous familial hypercholesterolemia (HeFH) and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent.
- 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.

In February 2015, we and Sanofi entered into an amended and restated ZALTRAP® agreement (Amended ZALTRAP Agreement). Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays us a percentage of aggregate net sales of ZALTRAP during each calendar year of between 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. Refer to "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP" below for further details of the Amended ZALTRAP Agreement. ZALTRAP is currently 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.

We have 13 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 12 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune® technology.

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Trap-based Clinical Programs

EYLEA

In Phase 3 clinical development for the treatment of Neovascular Glaucoma (NVG) (in Japan) in collaboration with Bayer HealthCare. As described below, aflibercept 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).

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. In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

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 in adults (Phase 3), atopic dermatitis in pediatric patients (Phase 2), asthma (Phase 3), nasal polyps in patients who also have chronic sinusitis (NPwCS) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).

REGN2810

Antibody to programmed cell death protein 1 (PD-1). Phase 1 clinical study in advanced malignancies initiated in the first quarter of 2015.

Antibody-based Clinical Program in Collaboration with Bayer HealthCare

REGN2176-3**

Combination product comprised of an antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 2 clinical study for the treatment of wet AMD initiated in the second quarter of 2015. Fast Track designation received from the FDA for the treatment of patients with wet AMD.

Antibody-based Clinical Program in Collaboration with Mitsubishi Tanabe Pharma

Fasinumab (REGN475)*

Antibody to Nerve Growth Factor (NGF). Phase 2b/3 study (16-weeks) in pain due to osteoarthritis initiated in the second quarter of 2015.

Antibody-based Clinical Programs Developing Independently

REGN2222*

Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. Phase 3 clinical study in RSV initiated in the second quarter of 2015.

Evinacumab (REGN1500)*

Antibody to Angptl-3. Phase 2 clinical study for the treatment of dyslipidemia in homozygous familial hypercholesterolemia initiated in the first quarter of 2015. Partial clinical hold that excluded women of childbearing potential was lifted by the FDA in the third quarter of 2015.

REGN1033*

Antibody to myostatin (GDF8). Phase 2 monotherapy clinical development in skeletal muscle disorders completed. Combination therapy plans are in development. In the second quarter of 2015, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN1033.

REGN1908-1909*

Antibody to Feld1 in Phase 1/Phase 2 clinical development against allergic disease.

REGN1979

Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia.

Nesvacumab/aflibercept (REGN910-3)**
Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 1 clinical development for the treatment of wet AMD and DME completed.

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* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate.
** Antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications, and antibodies targeting the Ang2 receptor and ligand in ophthalmology were previously included in our antibody collaboration with Sanofi. Under the terms of our agreements, Sanofi is entitled to receive potential development milestones and royalties on any future sales of the product candidate.
REGN1400, an antibody to ErbB3, REGN1154, an antibody against an undisclosed target, and REGN1193, an antibody to glucagon receptor (GCGR), each of which were previously in Phase 1 studies, 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.
Marketed Products
EYLEA (aflibercept) Injection
We commenced sales of EYLEA in the United States for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in the third quarter of 2014, and macular edema following RVO in the fourth quarter of 2014. In addition, in March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Outside the United States, Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME in the third quarter of 2014, and mCNV in Japan in the fourth quarter of 2014. In February and June 2015, the European Commission and the Japanese Ministry of Health, Labour and Welfare (MHLW), respectively, approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. In October 2015, the European Commission approved EYLEA for the treatment of visual impairment due to 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 various indications pending in other countries.
We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare markets, 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 $2,676.0 million in 2015, compared to $1,736.4 million in 2014 and $1,408.7 million in 2013. Bayer HealthCare records revenue from sales of EYLEA outside the United States, which were $1,413.3 million in 2015, compared to $1,038.5 million in 2014 and $472.1 million in 2013.
Praluent (alirocumab) Injection
In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In addition, in September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed

dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent. Under our collaboration agreement, Sanofi records product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States. We and Sanofi share profits and losses from sales of Praluent.

Net product sales of Praluent were $10.5 million in 2015.

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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 $13.5 million in 2015, $14.4 million in 2014, and $17.1 million in 2013.

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 RVO 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.

Neovascular Glaucoma

NVG is a secondary glaucoma triggered by the formation of new blood vessels (neovascularization) on the iris and the anterior chamber angle. Neovascularization restricts aqueous outflow and consequently elevates intraocular pressure (IOP). NVG is a serious condition that may lead to permanent loss of vision, a persistently painful eye, and, especially in the advanced stages, is unlikely to respond to treatment. NVG is caused by eye diseases leading to retinal ischemia, mainly CRVO, proliferative diabetic retinopathy (PDR), and ocular ischemic syndrome (OIS).

NVG meets the criteria for an orphan indication in Japan where the estimated number of NVG patients is 30,000 to 40,000. In the second quarter of 2015, Bayer HealthCare initiated a Phase 3 study in Japan to assess the efficacy and safety of intravitreal administration of aflibercept in comparison to sham treatment on the change in IOP in patients with NVG.

Late-Stage Antibody-based Clinical Programs

Praluent 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 cholesterol (LDL-C) 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. Similar to statins, PCSK9 impacts the number of available LDL receptors and therefore plays a key role in modulating LDL-C levels in the body. PCSK9 is a secreted protein that 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 (CHD). We used our VelocImmune technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called Praluent, that is intended to lower LDL cholesterol.

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Clinical Programs

Phase 3 ODYSSEY Program. We and Sanofi initiated the global Phase 3 ODYSSEY program for Praluent in 2012. The ODYSSEY program consists of more than 25,000 patients, and includes 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, which is fully enrolled and is expected to be completed in 2017. 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 and ODYSSEY CHOICE II. Patients in the ODYSSEY CHOICE I trial received Praluent 300 milligrams (mg) (most in combination with statins) every four weeks and patients in the CHOICE II trial received Praluent 150 mg monotherapy and in combination with non-statin lipid lowering therapy every four weeks.

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 Biologics License Application (BLA) for U.S. regulatory approval of Praluent was submitted, and accepted by the FDA in January 2015. 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. In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In addition, in September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

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 trials dosing every four weeks, 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 adverse events (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.

ODYSSEY JAPAN was a trial that evaluated Praluent (n =144) compared to placebo (n =72), both on top of standard care, in Japanese patients with hypercholesterolemia, with either HeFH or at high CV risk, and who could not reach their LDL-C treatment goal as defined by the Japan Atherosclerosis Society (JAS) guidelines despite lipid-lowering treatments that included statins. The mean LDL-C value at baseline was 141.2 mg/dL. Patients were initially randomized to receive either Praluent 75 mg every two weeks administered as a single 1 mL injection, or placebo. Patients in both groups received statins, with or without other lipid-lowering therapies. In July 2015, we and Sanofi announced that the Phase 3 ODYSSEY JAPAN trial met its primary endpoint. At week 24, patients in the Praluent group experienced an average 64% greater reduction from baseline in their LDL-C when added to current standard of care including statins, compared to standard of care alone ($p<0.0001$). Patients were started on the lower dose of 75 mg, with the option to adjust their dose to 150 mg if they had not achieved their LDL-C goal (as defined by the JAS guidelines) at week 8. At week 24, 97% of patients in the Praluent group reached their LDL-C treatment goal, compared to 10% for placebo ($p<0.0001$). Ninety-nine percent of Japanese patients who received Praluent at week 8 remained on the initial 75 mg dose, while 1% of patients had their dose adjusted to receive 150 mg every two weeks, also as a single 1 milliliter (mL) injection. The most common adverse events (occurring in at least 5% of patients in

the Praluent group) were nasopharyngitis, injection site reaction, and back pain. In July 2015, results were presented at the Annual Scientific Meeting of the JAS in Sendai, Japan.

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.

Rheumatoid Arthritis

Phase 3 Studies. In 2013, we and Sanofi announced that in the 52 week 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

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MTX improved disease signs and symptoms as well as physical function, and inhibited progression of joint damage. Additional data from the trial were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2015.

In the second quarter of 2015, we and Sanofi announced that in the 24 week SARIL-RA-TARGET Phase 3 clinical trial in adult patients with active RA who were inadequate responders or intolerant of TNF-alpha inhibitors, sarilumab treatment in combination with non-biologic disease modifying anti-rheumatic drugs (DMARD) therapy improved disease signs and symptoms, as well as physical function. Data from this trial were subsequently presented at the annual meeting of the American College of Rheumatology (ACR) in November 2015. A BLA for U.S. regulatory approval of sarilumab was accepted for review by the FDA in December 2015. The target date for an FDA decision on the BLA is October 30, 2016.

A summary of primary endpoints and most common AEs for the MOBILITY and TARGET trials is as follows:

Completed Efficacy and Safety Studies*

Study	Patient group	Primary efficacy endpoints**			Safety findings
		ACR[a] 20/50/70	HAQ-DI[b]	mTSS[c]	
MOBILITY (n=1,197)					
150mg + MTX (n=400)	Moderate to severe active RA with inadequate response to MTX	58/37/20 (p<0.0001 vs. placebo)	-0.53 (p<0.0001 vs. placebo)	0.90 (p<0.0001 vs. placebo)	Infections, neutropenia, injection site reactions, and increased transaminases
200mg + MTX (n=398)		66/46/25 (p<0.0001 vs. placebo)	-0.55 (p<0.0001 vs. placebo)	0.25 (p<0.0001 vs. placebo)	
Placebo + MTX (n=399)		33/17/7	-0.29	2.78	
TARGET (n=546)					
150mg + DMARD (n=181)	Moderate to severe active RA with inadequate response to, or intolerant of, one or more tumor necrosis factor-alpha (TNF-alpha) inhibitors	56/37/20[d] (p<0.0001 vs. placebo for ACR20 and ACR50)	-0.46 (p=0.0007 vs. placebo)	NA	Infections, neutropenia, injection site reactions, and hypertriglyceridemia
200mg + DMARD (n=184)		61/41/16[e] (p<0.0001 vs. placebo for ACR20 and ACR50)	-0.47 (p=0.0004 vs. placebo)		
Placebo + DMARD (n=181)		34/18/7	-0.26		

* - represent completed, placebo-controlled, double-blind efficacy studies

** - in MOBILITY, proportion of patients achieving ACR20 at week 24, change from baseline in HAQ-DI at week 16, and change from baseline mTSS at week 52 were co-primary endpoints. In TARGET, proportion of patients achieving ACR20 at week 24 and change from baseline in HAQ-DI at week 24 were co-primary endpoints

NA = not applicable

a.ACR = American College of Rheumatology score

b.HAQ-DI = the Health Assessment Question-Disability Index

c.mTSS = van der Heijde modified total Sharp score

d.p<0.0002 vs. placebo for ACR70

e.p<0.0056 vs. placebo for ACR70

Completed Safety Studies

Study	Patient group	Primary endpoint

			Study met primary endpoint?
ASCERTAIN (n=202)	Moderate to severe active RA with inadequate response to, or intolerant of, one or more TNF-alpha inhibitors	Assess safety of two subcutaneous doses of sarilumab and tocilizumab in combination with DMARDs	Yes
EASY (n=217)	Completed patients from MOBILITY, TARGET, or ASCERTAIN trials	Product technical failures	Yes

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Additional results from the Phase 3 studies will be presented at upcoming medical congresses.

We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-ONE, SARIL-RA-MONARCH, and SARIL-RA-KAKEHASI (in Japan). In addition, the SARIL-RA-HARUKA long-term safety trial was initiated in Japan in the first quarter of 2015. In the second quarter of 2015, an open-label, randomized, parallel group, single-dose Phase 1 study to assess the safety of IL-6 receptor blockade with sarilumab or tocilizumab monotherapy in Japanese patients with RA was also initiated. 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 inhibitor therapy. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, or SARIL-RA-ONE are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.

Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. SARIL-NIU-SATURN was a small Phase 2, randomized double-masked, placebo-controlled study (n=58) conducted to assess the effect of sarilumab on non-infectious uveitis of the posterior ocular segment. The primary endpoint of the study was the proportion of patients with a 2-step decrease in vitreous haze (based on a 9-point grading scale) or a steroid dose of less than 10 mg/day at week 16. Results of this study at the pre-specified primary endpoint, week 16, showed that compared with placebo patients, a greater proportion of patients randomized to sarilumab met the primary endpoint; however, this was not statistically significant. Approximately 70% of patients enrolled in the study had a baseline vitreous haze score of less than 2 as judged by the reading center, limiting our ability to interpret the vitreous haze component of the primary endpoint for these patients. Other indications of a positive effect of treatment with sarilumab compared to placebo included decreased average vitreous haze score, reduced macular edema and improved best-corrected visual acuity in patients presenting with more severe baseline ocular inflammation, and associated with improvement of leakage on fluorescein angiography. Overall, safety observations were consistent with the findings in studies of other indications with sarilumab. The study is ongoing and will continue through week 52, when we will discuss next steps with our collaborator Sanofi.

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, nasal polyps, and eosinophilic esophagitis. 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 2b Trial. In 2015, results from a Phase 2b dose-ranging study of dupilumab in adult patients with moderate-to-severe atopic dermatitis were published in The Lancet. All doses of dupilumab met the primary endpoint of a greater improvement in Eczema Severe Score Index (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 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 Investigator's Global Assessment (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

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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.

Phase 3 Study. In 2015, three Phase 3 trials in atopic dermatitis, LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, and LIBERTY AD SOLO 2, completed enrollment. Patients from these studies were transitioned to either the ongoing LIBERTY CONTINUE or LIBERTY AD Open label Extension trials. The LIBERTY AD Phase 3 clinical program consists 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, the determination that atopic dermatitis is a serious disease, and preliminary clinical evidence that indicates that the drug may demonstrate substantial improvement over existing therapies.

In December 2015, the United Kingdom (UK) Medicines & Healthcare products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) Designation to dupilumab in the short-term treatment of adult patients with severe atopic dermatitis who have responded inadequately to all available topical prescription treatments and/or systemic ciclosporin, or who are intolerant of or ineligible for such treatments. A PIM Designation is an early indication that a medicinal product is a promising candidate for the Early Access to Medicines Scheme (EAMS), in the treatment, diagnosis, or prevention of life-threatening or seriously debilitating conditions with unmet need. PIM Designation is the first step in a 2-step EAMS process that allows patients to be treated with dupilumab in advance of formal regulatory approval.

Phase 2 Trial in Pediatric Patients. In March 2015, a Phase 2 pharmacokinetic and safety study in pediatric patients (6-17 years of age) with moderate-to-severe atopic dermatitis was initiated and is fully enrolled.

Asthma

Phase 2b Study. In May 2015, we and Sanofi presented positive results from an interim analysis of a pivotal Phase 2b study of dupilumab in adult patients with moderate-to-severe asthma, who are uncontrolled despite treatment with inhaled corticosteroids and long-acting beta agonists (ICS/LABA), at the American Thoracic Society 2015 International Conference. The results of this study demonstrated that dupilumab added to standard-of-care therapy demonstrated fewer exacerbations and improved lung function across both the high and low baseline eosinophil groups of patients. As previously reported in 2014, the study met its primary endpoint of improving lung function in asthma patients with high blood eosinophil counts ((HEos), greater than or equal to 300 eosinophilic cells/microliter). New data presented on secondary endpoints at the American Thoracic Society 2015 International Conference included positive results in study patients with low blood eosinophil counts ((LEos), less than 300 eosinophilic cells/microliter), who are thought to be less likely to suffer from "allergic" asthma and thus less likely to respond to Type 2 helper T-cell (TH2) targeted therapies. Based on discussions with the FDA, this Phase 2b study may be considered one of two pivotal efficacy studies required for a potential dupilumab BLA in asthma.

The results presented in May 2015 focused on LEos asthma patients. In this population, patients treated every other week with either 200 mg or 300 mg doses of dupilumab showed a greater than 8% improvement in forced expiratory volume over one second ((FEV1), a standard measure of lung function) at week 12 ($p<0.001$), in comparison to placebo, both in combination with ICS/LABA. Additionally, the 200 mg and 300 mg every other week doses of dupilumab in combination with ICS/LABA showed 68% and 62% reductions, respectively, in adjusted annualized rate of severe exacerbations in the LEos population ($p<0.01$ and $p<0.05$), in comparison to placebo in combination with ICS/LABA. These results are consistent with previously reported positive results in HEos asthma patients and the overall patient population, in which the two every other week doses (200 mg and 300 mg) of dupilumab in combination with ICS/LABA demonstrated a statistically significant 12% to 15% improvement in FEV1 over placebo at week 12 and a 64% to 75% improvement in annualized rate of severe exacerbations over placebo. Dupilumab also significantly reduced mean fractional exhaled nitric oxide (FeNO) across both every other week doses tested (200 mg and 300 mg) and the three patient populations (overall, LEos and HEos), in a roughly dose-dependent manner. FeNO is recommended by the American Thoracic Society clinical practice guidelines to assess airway inflammation, since higher-than-normal levels of nitric oxide may be released when a patient has a chronic airway disease, such as asthma.

The most common AE was injection site reaction, which was more frequent in the dupilumab dose groups (13% to 25%) compared to placebo (12%). Other common AEs 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 across treatment groups (42% to 45% dupilumab; 46% placebo), as was the incidence of serious AEs (3% to 7% dupilumab; 5% placebo).

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 21.4 weeks. The primary endpoint of the study was improvement from baseline in FEV1 at week 12 in the HEos group.

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Phase 3 Study. A Phase 3 trial, LIBERTY ASTHMA QUEST, in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015. LIBERTY ASTHMA QUEST is expected to serve as the second required pivotal efficacy study, since, based on discussions with the FDA, the Phase 2b study will also be considered a pivotal efficacy study. The global, placebo-controlled Phase 3 study is expected to enroll more than 1,600 patients with uncontrolled persistent asthma and will evaluate two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

Nasal Polyposis

Phase 2 Trial. In 2013, a Phase 2 trial in NPwCS 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 NPwCS who did not respond to intranasal corticosteroids. The randomized, double-blind, placebo-controlled study enrolled 60 adult patients with moderate-to-severe NPwCS. Patients in the study received 300 mg of dupilumab, following an initial loading dose of 600 mg, or placebo, administered once per week subcutaneously for 16 weeks. 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 NPwCS 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 NPwCS 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 decrease 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.

Eosinophilic Esophagitis

Phase 2 Trial. A Phase 2 trial 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.

REGN2222 (RSV-F Antibody) for RSV

Overview

Respiratory Syncytial Virus, or RSV, is a virus that infects the lungs and breathing passages. It is the most common cause of bronchiolitis (inflammation of the small airways) and is the second most common cause of death, globally, in the first year of life. RSV results in a significant healthcare burden, as it is the leading cause of infant hospitalizations in the United States. In addition to hospitalizations, RSV frequently results in emergency department, urgent care, and physicians' office visits. It is estimated that about half of all children will have an RSV infection by their first birthday. REGN2222 is a fully human monoclonal antibody to the RSV-F protein. REGN2222 was generated using our VelocImmune technology.

Clinical Program

Based on clinical results from a Phase 1 study, a Phase 3 pivotal clinical study of REGN2222 (NURSERY Pre-Term) was initiated in the third quarter of 2015 and is currently enrolling patients.

In October 2015, the FDA granted Fast Track designation to REGN2222 for the prevention of serious lower respiratory tract disease caused by RSV.

Fasinumab (REGN475; NGF Antibody) for pain due to osteoarthritis

Overview

Persistent osteoarthritic pain represents a growing unmet medical need. Pain is a frequent reason for physician visits, a common reason for taking prescription medications, and a major cause of work disability and impaired quality of life. Targeting NGF is a potential advance in pain management. NGF expression is elevated in many acute and chronic painful conditions and NGF blockade has demonstrated efficacy in various animal models of pain. Fasinumab is a

fully human monoclonal antibody to NGF, generated using our VelocImmune technology.

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Clinical Program

A Phase 2b/3 clinical study (16-weeks) in patients with pain due to osteoarthritis was initiated in the second quarter of 2015. In the first quarter of 2016, the FDA confirmed that we may proceed with studies of longer than sixteen-week duration.

Research Programs

Our preclinical research programs include the areas of oncology/immuno-oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain and neurobiology, cardiovascular diseases, and infectious diseases.

In September 2015, we and the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) entered into an agreement to develop, test, and manufacture a monoclonal antibody therapy for the treatment of Ebola virus infection. HHS will provide initial funding of approximately $17.0 million to support our preclinical development and antibody manufacturing. HHS also has the option to provide for up to an additional $32.2 million for a Phase 1 study in healthy volunteers, and further manufacturing and development studies.

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 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.

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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 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC leverages de-identified clinical, genomic, and molecular data from human volunteers to identify 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 multiple approaches, including large population-based efforts as well as family- and founder-based approaches. RGC utilizes laboratory automation and innovative approaches to cloud computing to achieve high-quality throughput at a rate that currently exceeds 100,000 unique samples sequenced per year.

Central to the work of RGC is a collaboration with the Geisinger Health System of Pennsylvania. Geisinger collects samples from consented patient volunteers, while RGC performs sequencing and genotyping to generate de-identified genomic data. In addition, RGC has expanded on its foundational population-based collaboration with Geisinger with a growing number of other institutions worldwide, including Columbia University Medical Center, the Clinic for Special Children, Baylor College of Medicine, and SickKids in Toronto.

Collaboration Agreements

Collaborations with Sanofi

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 (Antibody Discovery Agreement) and a License and Collaboration Agreement (each as amended), collectively referred to as the Antibody Collaboration. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi was responsible for funding up to $160.0 million per year of our antibody discovery activities over the period from 2010-2017. However, in connection with the companies' July 2015 immuno-oncology collaboration as described below, the 2015-2017 amounts have been revised, and Sanofi is now responsible for funding up to $145.0 million in 2015, and up to $130.0 million in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Our discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will now be funded by Sanofi under the terms of the companies' new immuno-oncology collaboration. We lead the design and conduct of research activities under the Antibody Discovery Agreement, 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 Antibody Discovery Agreement, Sanofi has the option to license rights to the candidate under the License and Collaboration 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 as they are incurred by us, 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 have exercised our option to co-promote Praluent, sarilumab, and dupilumab in the United States. We have not exercised our option to co-promote Praluent outside the

United States; however, we retain the right to do so at a future date subject to the terms of the collaboration agreement. 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 $250.0 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.

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Immuno-Oncology. In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million (IO Discovery Budget) to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits, which consists of (i) $750.0 million in new funding and (ii) $75.0 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery Agreement, as described above. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of IND Applications, and clinical development through proof-of-concept. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized 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 IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. We will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal

or exceed $2.0 billion in any consecutive twelve-month period.

ZALTRAP. From September 2003 to February 2015, we and Sanofi were parties to a global collaboration (ZALTRAP Collaboration Agreement) for the development and commercialization of ZALTRAP. In February 2015, we and Sanofi entered into an Amended ZALTRAP Agreement. Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. We will also be paid for all quantities of ZALTRAP manufactured by us pursuant to a supply agreement through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation (which was approximately $461 million at December 31, 2014) to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement.

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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.

Since inception of the agreement, we have earned $110.0 million of development milestone payments and $165.0 million of sales milestone payments from Bayer HealthCare. During the first quarter of 2015, we earned the final potential milestone payment under our Bayer HealthCare collaboration agreement in connection with EYLEA outside the United States.

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 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 up-front 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 a total of $5.0 million of development milestone payments to us in the 2014, and an additional $5.0 million development milestone payment to us in 2015. We are eligible to receive a $10.0 million additional future development milestone payment from Bayer HealthCare, although this payment 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 EU 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.

Collaboration with Mitsubishi Tanabe Pharma

Fasinumab Asia. In September 2015, we entered into a collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) providing MTPC with development and commercial rights to fasinumab in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the MTPC Territories). In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment in 2015, and in the first quarter of 2016, MTPC

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became obligated to make an additional $45.0 million payment to us. We are also entitled to receive up to an aggregate of $170.0 million in development milestone and other contingent payments.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as MTPC has ceased developing or commercializing fasinumab in the MTPC Territories.

Manufacturing

We currently manufacture bulk drug materials at our manufacturing facilities in Rensselaer, New York, which consists of approximately 440,000 square feet of owned research, manufacturing, office, and warehouse space. We currently have approximately 76,000 liters of cell culture capacity at these facilities. At December 31, 2015, we employed approximately 1,325 people at our Rensselaer facilities.

In 2014, we acquired 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, Praluent, ARCALYST, and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform packaging, filling, finishing, labeling, distribution, laboratory testing, and other services related to the manufacture of EYLEA, Praluent, 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, a Market Research group, and a Market Access 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. These groups are fully functional to support our product and product candidates that we are independently developing and/or commercializing, and also work closely with our collaborators for co-developed products to develop marketing plans and forecasts and to develop and execute pre-launch market development programs.

We also have a full-service commercialization group to handle various aspects of our commercial programs. The group includes experienced professionals in the fields of marketing, communications, professional education, patient education and advocacy, reimbursement and market access, trade and distribution, commercial operations, commercial analytics, market research, and forecasting. Moreover, for EYLEA and Praluent, we have hired, trained, and deployed a field-based organization including regional sales directors, medical sales specialists, and reimbursement managers, each typically with a number of years of experience in the biopharmaceutical industry in a variety of therapeutic areas including oncology, ophthalmology, immunology, and inflammation. Hiring has commenced for our U.S. field teams for both sarilumab and dupilumab. We have approximately 70 field-based employees working on EYLEA and 330 field-based employees working on Praluent. We have significantly expanded the commercialization group to support the launch of Praluent in 2015. We outsource the warehousing and distribution of our finished drug products.

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

treating physicians.

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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, 2015, 2014, and 2013, we recorded 67%, 73%, and 76%, respectively, of our total gross product revenue from sales to a single distributor, Besse Medical, which is a subsidiary of AmerisourceBergen Corporation. We are also a party to collaboration agreements with Bayer HealthCare and Sanofi, whereby our collaborator is responsible for recording product sales of EYLEA outside the United States and global sales of Praluent, respectively.

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., Allergan, Inc., Eli Lilly and Company, AbbVie Inc., 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.

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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	Roche/Genentech	Wet AMD, DME, and macular edema following RVO	Worldwide
Ozurdex® (dexamethasone intravitreal implant)	Approved	Allergan	DME, RVO	Worldwide
Iluvien® (fluocinolone acetonide intravitreal implant)	Approved	Alimera Sciences	DME	United States, EU
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 (in collaboration with Roche/Genentech and Novartis)	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 and EYLEA)	Novartis	Wet AMD	—
Abicipar pegol (anti-VEGF-A-DARPin®)	In development (non-inferiority Phase 3 trial initiated in 2015 comparing dosing regimens of abicipar pegol and Lucentis)	Allergan	Wet AMD and related conditions	—
Bi-specific antibody RG7716	In development (Phase 2)	Roche/Genentech	Wet AMD	—

Lucentis Port Delivery System	In development (Phase 2)	Roche/Genentech	Wet AMD and related conditions	—
PF582, a biosimilar to Lucentis	In development (Phase 1/2)	Pfenex Inc. (in collaboration with Pfizer)	Wet AMD and related conditions	—
FYB201, a biosimilar to Lucentis	In development (Phase 3)	Formycon AG (in collaboration with Bioeq GmbH)	Wet AMD and related conditions	—
LMG324	In development (Phase 1/2)	Novartis	Wet AMD and related conditions	—

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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."

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

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication/Target	Territory
Repatha™ (evolocumab)	Approved	Amgen	PCSK9 inhibitor antibody; adjunct to diet and (i) maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C or (ii) other LDL-lowering therapies in patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-C	United States, Canada, EU, Japan
Bococizumab (RN316 / PF-04950615)	In development (Phase 3)	Pfizer	Antibody against PCSK9	—
LY3015014	In development (Phase 2)	Eli Lilly	Antibody against PCSK9	—
ALN-PCSsc	In development (Phase 2)	Alnylam Pharmaceuticals, Inc. (in collaboration with The Medicines Company)	RNAi molecule against PCSK9 (injectable, small molecule)	—
Anacetrapib	In development (Phase 3)	Merck	CETP-inhibitor (oral, small molecule)	—
AMG-899 (TA-8995)	In development (Phase 2)	Amgen	CETP Inhibitor (oral, small molecule)	—
ETC-1002 (bempedoic acid)	In development (Phase 2)	Esperion Therapeutics, Inc.	ACL-inhibitor (oral, small molecule)	—
CAT-2054	In development (Phase 2)	Catabasis Pharmaceuticals, Inc.	SREBP modulator (oral, small molecule)	—

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

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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, Roche/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.

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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 collaboration 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 collaboration 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
	RuYi	Gerilimzumab	In development (Phase 1)	Antibody against IL-6
Dupilumab (Phase 2/Phase 3) Target: IL-4R	GlaxoSmithKline	Nucala® (mepolizumab)	Approved	Antibody against IL-5
	Teva	Reslizumab	Submitted for regulatory approval	Antibody against IL-5
	Roche	Lebrikizumab	In development (Phase 3)	Antibody against IL-13
	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
	Amgen	AMG-157	In development (Phase 2)	Antibody against TSLP
Fasinumab (Phase 2b/ Phase 3) Target: NGF	Pfizer/Eli Lilly	Tanezumab	In development (Phase 3)	Antibody against NGF
	Johnson & Johnson	Fulranumab	In development (Phase 3)	Antibody against NGF
REGN2222 (Phase 3) Target: RSV-F	AstraZeneca	Synagis® (palivizumab) MEDI8897	Approved	Antibody against RSV-F protein

AstraZeneca/AIMM Therapeutics	In development (Phase 2)	Antibody against RSV-F protein

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."

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Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

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

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - We may be restricted in our development, manufacturing, and/or commercialization activities by 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 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 2030. However, we continue to file patent applications directed to improvements to these technology platforms.

Our patent portfolio also includes issued patents and pending applications relating to commercialized products 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, Praluent, ARCALYST, and ZALTRAP, these patents generally expire between 2020 and 2029. 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 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 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 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 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

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other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights is expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - We may be restricted in our development, manufacturing, and/or commercialization activities by 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").

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 our products and our product candidates (see Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of EYLEA - We and Bayer HealthCare are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we or Bayer HealthCare fail to maintain regulatory compliance for EYLEA, EYLEA marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition."; "Risks Related to Commercialization of Praluent - We and Sanofi are subject to significant ongoing regulatory obligations and oversight with respect to Praluent. If we or Sanofi fail to maintain regulatory compliance for Praluent, Praluent marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition."; and "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our 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.

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Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

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

Employees

As of December 31, 2015, we had approximately 4,300 full-time employees, of whom approximately 650 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).

Investors and other interested parties should note that we use our media and investor relations website (http://newsroom.regeneron.com) and our social media channels to publish important information about Regeneron, including information that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our media and investor relations website and the social media channels listed on our media and investor relations website, in addition to our SEC filings, press releases, conference calls, and webcasts.

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 successfully 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, 2015 and 2014, EYLEA

net sales in the United States represented 65% and 62% 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 expect that the continued commercial success of EYLEA will depend on many factors, including the following:

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- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA as compared to the dosing regimen of Lucentis, and the willingness of retinal specialists and patients to switch from Lucentis or off-label use of repackaged Avastin to EYLEA or to start treatment with 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 considered or 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.

More detailed information about the risks related to the commercialization of EYLEA is provided in the risk factors below.

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

We and Bayer HealthCare 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 or Bayer HealthCare fail to maintain regulatory compliance for EYLEA for its currently approved indications (including for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain"), EYLEA marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales" below.

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

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. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - 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" below.

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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 large 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 large 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. For example, 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. 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. In addition, 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. 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 (an overview of the competitive landscape for EYLEA is provided in Part I, Item 1. "Business - Competition - EYLEA"). For example, Novartis and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of various 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. (in collaboration with Pfizer) is developing PF582 (currently in a Phase 1b/2a trial in patients with wet AMD), and Formycon AG (in collaboration with bioeq GmbH) is developing FYB201 (currently in a Phase 3 trial in patients with wet AMD). Other competitive or potentially competitive products include Allergan's Ozurdex (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 (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, Genentech/Roche is developing a Lucentis port delivery system implant (currently in a Phase 2 study in patients with wet AMD). Novartis is developing RTH258 (ESBA1008), 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 and EYLEA in December

2014. Allergan is developing abicipar pegol (an anti-VEGF-A DARPin) for wet AMD and related conditions (currently studied in Phase 3 trials against Lucentis as a comparator drug). 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 (in collaboration with Genentech/Roche) 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/Roche is developing a bi-specific antibody targeting both VEGF and Ang2 for wet AMD (currently in a Phase 2 trial in patients with wet AMD). Competitors are also developing eye-drop formulations, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

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In addition, ophthalmologists are using with success off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, Avastin, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged Avastin 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 exacerbate the competitive challenge which EYLEA faces in this or other eye indications for which it is 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.

We rely on our collaboration with Bayer HealthCare for commercializing EYLEA.

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 for EYLEA outside the United States.

Under the terms of our license and collaboration agreement with Bayer HealthCare (which is terminable by Bayer HealthCare at any time upon six or twelve months' advance notice), 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. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, 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. For additional information regarding our collaboration with Bayer HealthCare, see "Risks Related to Our Reliance on Third Parties - 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" below.

Sales of EYLEA recorded by us and Bayer HealthCare could be reduced by imports from countries where EYLEA may be available at lower prices.

Our sales of EYLEA in the United States and Bayer HealthCare's sales of EYLEA in other countries may be reduced if EYLEA is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. 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 are 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 marketed in those nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of EYLEA in a particular market or reduce our or Bayer HealthCare's sales, thereby adversely affecting our results of operations. 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 derived from EYLEA sales could be reduced.

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Risks Related to Commercialization of Praluent

If we and Sanofi are unable to successfully commercialize Praluent, our business, prospects, operating results, and financial condition may be materially harmed.

We expect that the commercial success of Praluent will depend on many factors, including the following:

- effectiveness of the commercial strategy in and outside the United States for the marketing of Praluent, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- our and Sanofi's ability to effectively communicate to the marketplace the benefits of Praluent;
- the ability of patients and 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 and Sanofi's ability to maintain sales of Praluent in the face of competitive products, including Amgen's Repatha, as well as product candidates currently in clinical development;
- the results of post-approval studies of Praluent (including the ongoing ODYSSEY OUTCOMES trial prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit), whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about Praluent (or data about products similar to Praluent that implicate an entire class of products or are perceived to do so);
- our ability to meet the demand for commercial supplies of Praluent;
- the effect of existing and new health care laws and regulations currently being considered or 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; and
- maintaining and successfully monitoring commercial manufacturing arrangements for Praluent with third parties who perform fill/finish or other steps in the manufacture of Praluent to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities.

More detailed information about the risks related to the commercialization of Praluent is provided in the risk factors below.

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

We and Sanofi are subject to significant ongoing regulatory obligations and oversight with respect to Praluent for its currently approved indications in the United States and the EU. If we or Sanofi fail to maintain regulatory compliance for Praluent for its currently approved indications (including because Praluent does not meet the relevant endpoints of any required post-approval studies, such as the ongoing ODYSSEY OUTCOMES trial, or for any of the other reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain"), Praluent marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales" below.

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

Serious complications or serious, unexpected side effects in connection with the use of Praluent could materially harm our business, prospects, operating results, and financial condition. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining

Approval of Our Product Candidates and New Indications for Our Marketed Products - 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" below.

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Sales of Praluent are dependent on the availability and extent of reimbursement from third-party payers in the United States and other countries, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales in the United States of Praluent are dependent, in large 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 Praluent in other countries are dependent, in large part, on similar reimbursement mechanisms and programs in those countries.

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. For example, pharmacy benefit management companies often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one pharmacy benefit management company to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of Praluent. If Praluent is not included within an adequate number of formularies, adequate reimbursement levels are not provided, or the eligible insured patient population for Praluent is limited, this could have a material adverse effect on our and Sanofi's ability to commercialize Praluent.

In the United States, there also 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 Praluent. Since Praluent is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers in the United States and other countries, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize Praluent 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 Praluent is subject to strong competition.

There is significant actual and potential future competition for Praluent (an overview of the competitive landscape for Praluent is provided in Part I, Item 1. "Business - Competition - Praluent"). Amgen's PCSK9 program is currently the most advanced of the competitors, having already received regulatory approval from the FDA and marketing authorization from the European Commission for its PCSK9 inhibitor Repatha. Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Several other companies, including Pfizer, also have development programs for antibodies against PCSK9. Alnylam, in collaboration 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. Certain late-stage inhibitors of cholesterylester transfer protein (CETP), such as Merck's anacetrapib, lower LDL-C and may be launched with supporting data from outcomes trials prior to the completion of our own outcomes trial for Praluent. Other oral agents for lowering LDL-C that may potentially compete with Praluent include ETC-1002 and CAT-2054, which are being developed by Esperion Therapeutics and Catabasis Pharmaceuticals, respectively.

We rely on our Antibody Collaboration with Sanofi for commercializing Praluent.

In accordance with the terms of our Antibody Collaboration with Sanofi, we have elected to co-promote Praluent with Sanofi in the United States. As such, we continue to rely in part on Sanofi's sales and marketing organization in the United States. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of Praluent may be materially affected. Sanofi also maintains other important responsibilities relating to Praluent in the United States. For example, Sanofi records product sales and cost of sales for Praluent in the United States, serves as the lead regulatory party (e.g., is responsible for regulatory filings and negotiations relating to Praluent in the United States), and leads negotiations with payors.

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We also rely on Sanofi for sales, marketing, and distribution of Praluent in countries outside the United States. If we and Sanofi are unsuccessful in commercializing Praluent, or if Sanofi terminates the Antibody Collaboration with us, our business, prospects, operating results, and financial condition may be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for Praluent. Therefore, termination of our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of Praluent, particularly outside the United States. For additional information regarding our Antibody Collaboration with Sanofi, see "Risks Related to Our Reliance on Third Parties - If any of our collaborations 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" below.

Sales of Praluent recorded by Sanofi could be reduced by imports from countries where Praluent may be available at lower prices.

Sales of Praluent recorded by Sanofi in the United States and other countries (which impact our share of any profits or losses from the commercialization of Praluent under our Antibody Collaboration with Sanofi and, therefore, our results of operations) may be reduced if Praluent is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our Antibody Collaboration with Sanofi, pricing and reimbursement for Praluent outside the United States is the responsibility of Sanofi. Prices for Praluent in territories outside the United States are 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 sales of Praluent in the United States that are recorded by Sanofi may be reduced if Praluent marketed in those bordering nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of Praluent in a particular market or the sales recorded by Sanofi, thereby adversely affecting our results of operations. 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 derived from Praluent sales could be reduced.

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

If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our 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.

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.

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

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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, 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.

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,

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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.

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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 an additional indication, and aflibercept is being studied as a combination product. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize aflibercept. 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. 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 aflibercept (such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), 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 further development and/or commercialization of aflibercept.

The potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing ODYSSEY OUTCOMES trial. There is no guarantee that Praluent will meet the relevant endpoints of this trial. In addition, there are potential safety concerns associated with PCSK9 inhibitor antibodies such as Praluent that may limit our ability to further successfully develop and/or commercialize Praluent, including new-onset diabetes mellitus, injection-site reactions, hypersensitivity, immunogenicity, demyelination, and changes in neurocognitive function. There also are risks inherent in subcutaneous injections, including subcutaneous injections with Praluent, such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. These and other complications or side effects could harm further development and/or commercialization of Praluent.

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.

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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.

Some of our products and, if approved, product candidates may be used with drug delivery devices, which have their own regulatory and other risks.

Some of our products (such as Praluent) are used and, if approved, some of our product candidates may be used in combination with a drug delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. The success of our product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application, our product candidates used with such drug delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. In addition, some of these drug delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply the devices; to conduct the studies required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

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 current or former 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 third-party observations that argue against patentability or 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 was 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. Post-grant review proceedings are increasingly common in the United States and are 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.

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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 initiated by us relating to our European Patent No. 1,360,287, our European Patent No. 2,264,163, and our U.S. Patent No. 8,502,018, all 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, 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 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; dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, nasal polyposis, and eosinophilic esophagitis; REGN2222, an antibody targeting RSV-F; and fasinumab, an antibody to NGF. 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. As described in Part I, Item 3. "Legal Proceedings" of this report, we and Sanofi-Aventis U.S. LLC initiated invalidity actions against patents jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies by host cells. We currently produce our antibody product and antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST nor EYLEA is a recombinant antibody. Genentech has licensed these patents to several different companies under confidential license agreements. If we desire a license for any of our antibody products or product candidates as part of a settlement for these invalidity actions 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 products or product 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 products or 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 products or 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

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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 an 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 regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened. The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

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

Our manufacturing facilities would be inadequate to produce the active pharmaceutical ingredients of (a) EYLEA, Praluent, 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 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 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.

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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 governmental permits, 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, Praluent, and ARCALYST and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture 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, Praluent, 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 (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of EYLEA or Praluent 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 and are in the process of building a large-scale manufacturing facility in Limerick, Ireland. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products 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.

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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 collaborators or contract manufacturers.

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and 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 our marketed products and 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 marketed products and product candidates, which could materially and adversely affect our business and future prospects.

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

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

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

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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.

For a description of additional risks relating specifically to the commercialization of EYLEA and Praluent, see above under "Risks Related to Commercialization of EYLEA" and "Risks Related to Commercialization of Praluent," respectively.

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."

There is also significant actual and potential future competition for Praluent, the PCSK9 antibody we are developing and commercializing in collaboration with Sanofi, as described in greater detail above under "Risks Related to Commercialization of Praluent - The commercial success of Praluent 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 (an overview of the competitive landscape for our antibody programs that are in late-stage clinical development is provided in Part I, Item 1. "Business - Competition - Monoclonal Antibodies"). For example, Pfizer (in collaboration with Eli Lilly) and Johnson & Johnson are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (Actemra) for the treatment of rheumatoid arthritis that would compete with sarilumab, our IL-6R antibody, if it is approved. In addition, several other companies, including Johnson & Johnson (in collaboration with GlaxoSmithKline), Alder Biopharmaceuticals, Ablynx (in collaboration

with AbbVie), R-Pharm, and Pfizer have antibodies against IL-6 or IL-6R in clinical development. 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 collaboration with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). GlaxoSmithKline's Nucala may also compete with dupilumab, if dupilumab is approved.

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For RSV, competitors have marketed antibodies as well as antibodies in clinical development, including AstraZeneca (in collaboration with AIMM Therapeutics).

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. 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.

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 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

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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, 2015 and 2014, we recorded 67% and 73%, 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.

If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and do not currently have an organization for the sales, marketing, and distribution of marketed products outside the United States. There may be circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to exercise our option to co-promote a product outside the United States or commercialize a particular product independently; we are unable to find an appropriate collaborator; or our existing collaborator decides not to opt in, decides to opt out, or breaches its obligations to us with respect to a particular product.

In order to commercialize any products outside the United States, we must build our sales, marketing, distribution, managerial, and other non-technical capabilities in the relevant markets or make arrangements with third parties to perform these services, which would likely be expensive and time consuming and could delay product launch in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop commercial capabilities outside the United States within an acceptable time frame or at all. These and other difficulties relating to commercializing our products outside the United States may severely harm our business, prospects, operating results, and financial condition.

For additional risks relating to commercialization of EYLEA and Praluent outside the United States, see also "Risks Related to Commercialization of EYLEA - We rely on our collaboration with Bayer HealthCare for commercializing EYLEA" and "Risks Related to Commercialization of Praluent - We rely on our Antibody Collaboration with Sanofi for commercializing Praluent," respectively.

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. To the extent we maintain product liability insurance in relevant periods, such 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.

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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.

The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA's review of promotional activities includes healthcare provider-directed and direct-to-consumer advertising as well as sales representatives' communications. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations.

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

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

As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any "transfers of value" made to U.S. prescribers and certain other healthcare providers and teaching hospitals. Information provided by companies is aggregated and posted annually on an "Open Payments" website, which is managed by the Centers for Medicare & Medicaid Services, the agency responsible for implementing these disclosure requirements. We will need to continue to dedicate significant resources to comply with these requirements. The PPACA also includes various provisions designed to strengthen 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 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. Many of these requirements and standards are new or 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. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

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,

trade restrictions and sanctions, 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.

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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.

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

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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 sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

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 Internal Revenue Service 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. Changes in tax laws of various jurisdictions in which we do business could also result from the base erosion and profits shifting, or BEPS, recommendations by the Organization for Economic Co-operation and Development. If these recommendations (or other changes in law) were adopted by the countries in which we do business, it could adversely affect our provision for income tax and our current rate.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or 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, has entered into collaborations with research institutions, including the Geisinger Health System, which are subject to such regulations. Regeneron is not currently classified as a covered entity or business associate under HIPAA and thus is not subject to its requirements or penalties. 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, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring

notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs and research collaborations outside the U.S. implicate international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it. Our activities outside the U.S. impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our 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

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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 health 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. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. 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.

Risks Related to Our Reliance on Third Parties

If any of our collaborations 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, as well as our immuno-oncology research and development programs. Sanofi has committed to reimburse us for up to (i) $405 million of the costs of our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets under our Antibody Discovery Agreement and (ii) $825 million of the costs of our efforts to identify and validate potential immuno-oncology targets and develop fully-human therapeutic antibodies against such targets under the IO Discovery and Development Agreement. Sanofi also initially funds almost all of the development expenses incurred in connection with the clinical development of product candidates (i) that Sanofi elects to co-develop with us under our Antibody Collaboration and (ii) for which Sanofi is the principal controlling party under our IO Collaboration. In addition, Sanofi initially funds half of the development expenses incurred in connection with the clinical development of product candidates for which we are the principal controlling party under our IO Collaboration. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us under our Antibody Collaboration (such as Praluent, sarilumab, and dupilumab) or for which Sanofi is the principal controlling party under our IO Collaboration, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we also rely on Sanofi to lead (i) the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us under our Antibody Collaboration and (ii) the commercialization efforts outside the Unites States to support all products that are co-developed by Sanofi and us under our IO Collaboration (as well as the commercialization efforts in the United States to support all products for which Sanofi is the principal controlling party under our IO Collaboration).

If Sanofi does not elect to co-develop the product candidates that we discover or opts out of their development under our Antibody Collaboration or our IO Collaboration, 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, REGN2222, and REGN1033, and decided not to opt in to the evinacumab and other programs.

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If Sanofi terminates any of the collaborations with us 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. If Sanofi does not perform its obligations with respect to the product candidates that it elects to co-develop, our ability to develop, manufacture, and commercialize these product candidates will be significantly adversely affected. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for products commercialized under our Antibody Collaboration, such as Praluent (see also "Risks Related to Commercialization of Products - If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected" above). Termination of our Antibody Collaboration would create substantial new and additional risks to the successful development and commercialization of Praluent, particularly outside the United States.

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 and maintain 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 (see also "Risks Related to Commercialization of Products - If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected" above). 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 our marketed products 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 and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators' arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

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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 Praluent 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.

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. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may provide access to our confidential information to such third parties and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

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 attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

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 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.

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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 and borrowing availability under our revolving credit facility, 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 commercialization of EYLEA and Praluent 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 obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of EYLEA, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

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

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, 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, 2015, we had $809.1 million in cash and cash equivalents and $868.3 million in marketable securities (including $31.5 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;
- 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;

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- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA and Praluent;
- 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.

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, 2015, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 46.4% 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, 2015. As of December 31, 2015, Sanofi beneficially owned 23,108,570 shares of our Common Stock, representing approximately 22.5% 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 Antibody Discovery 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

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Stock through open market purchases and direct purchases from shareholders. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase (subject to market conditions, including the price and availability of shares of our Common Stock, and legal and regulatory requirements) additional shares of our Common Stock to maintain and opportunistically increase its beneficial ownership on a percentage basis 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, 2015, holders of Class A Stock held 15.7% 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, 2015:

- our current executive officers and directors beneficially owned 10.5% 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, 2015, and 21.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2015; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 46.4% 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, 2015. In addition, these five shareholders plus our Chief Executive Officer held approximately 52.4% 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, 2015.

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 and resigned on November 10, 2015. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to designate a successor designee.

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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, or the Notes, we entered into convertible note hedge transactions with four financial institutions, or 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, 2015, an aggregate principal amount of $11.2 million of the Notes and 2,109,098 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 have entered 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 continue to exercise options under the convertible note hedge transactions whenever Notes are converted. In order to unwind their hedge position with respect to the options we exercise, the hedge counterparties and/or their affiliates may sell shares of our Common Stock or other securities in secondary market transactions or unwind various derivative transactions with respect to our Common Stock during the cash settlement averaging period for the converted Notes. The effect, if any, of any of these transactions and activities on the trading price of our Common Stock or the Notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our Common Stock and the value of the Notes. The derivative transactions that the hedge counterparties and/or their affiliates expect to enter into to hedge these transactions may include cash-settled equity swaps referenced to our Common Stock. In certain circumstances, the hedge counterparties and/or their affiliates may have derivative positions that, when combined with the hedge counterparties' and their affiliates' ownership of our Common Stock, if any, would give them economic exposure to the return on a significant number of shares of our Common Stock.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements and our 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 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;
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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."

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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; or (v) other specified events, such as a liquidation or dissolution of our company.

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

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, 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 and to use our reasonable efforts to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains a specified equity interest in us. As described above under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management," a Sanofi designee served on our board of directors from April 2014 to November 2015, and Sanofi has disclosed its intention to designate a successor designee. 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. Below is a summary of such properties. 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.

Tarrytown, New York

At our Tarrytown, New York location, we lease approximately 1,108,000 square feet of laboratory and office space. This includes approximately 297,000 square feet of laboratory and office space constructed in two new buildings, which were completed in 2015.

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Additionally, in April 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our current Tarrytown, New York location for an aggregate purchase price of $73.0 million. We intend to develop this property to accommodate and support our growth, primarily in connection with expanding our existing research and development and office space.

Rensselaer, New York

We own facilities in Rensselaer, New York totaling approximately 440,000 square feet of research, manufacturing, office, and warehouse space. We also lease approximately 75,000 square feet of additional laboratory and office space.

Limerick, Ireland

In 2014, we acquired a 400,000 square foot manufacturing facility in Limerick, Ireland. 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.

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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, '018 Patent, and '163 Patent

We are parties to patent infringement litigation initiated by us involving our European Patent No. 1,360,287 (the '287 Patent), our European Patent No. 2,264,163 (the '163 Patent), and our U.S. Patent No. 8,502,018 (the '018 Patent), all 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, we claim infringement of several claims of the '287 Patent, the '163 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, the '163 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 (EPO) on April 3, 2014. The case against Kymab and the case against Novo Nordisk were consolidated in the Patents Court in London in May 2014. On October 19, 2015, following the grant of the '163 Patent by the EPO, we added an infringement claim based on the '163 Patent to our '287 Patent infringement litigation against Kymab and Novo Nordisk in the English High Court of Justice, Chancery Division, Patents Court, in London. Both Kymab and Novo Nordisk counterclaimed alleging invalidity of the '163 Patent. In November 2015, we withdrew our claims against Novo Nordisk, while preserving our rights to pursue an infringement action against it in jurisdictions other than the United Kingdom. A trial to adjudicate the claims of infringement and invalidity of the '287 Patent and the '163 Patent was held from November 16, 2015 through December 8, 2015. On February 1, 2016, the court issued a final judgment, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. We plan to appeal this decision.

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 2, 2015, the United States District Court for the Southern District of New York issued an opinion and order in our '018 Patent infringement litigation against Merus B.V. finding that the '018 Patent was procured by inequitable conduct, thus rendering it unenforceable. On December 17, 2015, we filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit.

Our '287 Patent was also the subject of opposition proceedings in the 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. On November 9, 2015, the Technical Board of Appeal of the EPO reversed the decision of the Opposition Division and found the amended claims of the '287 Patent were valid. A final written decision is expected to be issued in the first quarter of 2016.

Proceedings Relating to Praluent (alirocumab) Injection

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 (the '165 Patent), and 8,859,741 (the '741 Patent) in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 (the '914 Patent) 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

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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.

On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint, which was granted on January 29, 2016. As amended, the complaint alleges, among other things, willful infringement of the asserted patents, which would allow the court to increase damages up to three times the amount assessed if the court finds willful infringement. On October 20, 2015, the District Court issued its claim construction order, in which it defined the meaning of certain disputed claim terms; none of the court's rulings was dispositive of the issues in the case. On November 3, 2015, pursuant to court order, the patents asserted by Amgen were narrowed to the '165, '741, and '914 Patents. The trial is currently set to begin on March 7, 2016, and a permanent injunction hearing (which would be held if the court finds infringement of a valid patent claim by us and Sanofi) is currently scheduled to begin on March 23, 2016.

Proceedings Relating to Patents Owned by Genentech and City of Hope

On July 27, 2015, we and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Western Division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent (alirocumab), of U.S. Patent No. 7,923,221 jointly owned by Genentech, Inc. (Genentech) and City of Hope relating to the production of recombinant antibodies by host cells. On the same day, we and Sanofi-Aventis U.S. LLC initiated an inter partes review in the United States Patent and Trademark Office (USPTO) seeking a declaration of invalidity of certain claims of U.S. Patent No. 6,331,415 jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies by host cells. On February 5, 2016, the USPTO instituted an inter partes review of the validity of most of the patent claims for which review had been requested. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by us and Sanofi in the District Court and counterclaimed, alleging that we and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016.

Proceedings Relating to Shareholder Derivative Claims

On December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former non-employee members of our board of directors, the Chairman of the board of directors, our Chief Executive Officer, and our Chief Scientific Officer as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2013 and 2014. The complaint seeks damages in favor of Regeneron for the alleged breaches of fiduciary duties and unjust enrichment; changes to Regeneron's corporate governance and internal procedures; invalidation of Regeneron's 2014 Long-Term Incentive Plan with respect to the individual defendants' compensation and a shareholder vote regarding the individual defendants' equity compensation; equitable relief, including an equitable accounting with disgorgement; and award of the costs of the action, including attorneys' fees. We intend to move to dismiss the shareholder derivative complaint. Pursuant to our By-Laws and the New York Business Corporation Law, expenses in connection with the foregoing are being advanced by us to certain current and former directors and/or officers.

On or about December 15, 2015, we received a shareholder litigation demand upon our board of directors made by a purported Regeneron shareholder. The demand asserts that the current and certain former non-employee members of the board of directors and the Chairman of the board of directors excessively compensated themselves in 2013 and 2014. The demand requests that our board of directors investigate and bring legal action against these directors for breach of fiduciary duty, unjust enrichment, and corporate waste, and implement internal controls and systems designed to prohibit and prevent similar actions in the future. Our board of directors, working with outside counsel, investigated the allegations in the demand and the shareholder derivative complaint, and has determined to defer its decision on the demand until the court rules on the forthcoming motion to dismiss the shareholder derivative complaint, as discussed above.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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
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
2015		
First Quarter	$495.50	$393.00
Second Quarter	544.00	433.47
Third Quarter	605.93	435.52
Fourth Quarter	592.59	448.10

As of February 4, 2016, there were 212 shareholders of record of our Common Stock and 24 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.

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STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The NQ US Benchmark Pharma TR Index, and (ii) Standard & Poor's 500 Stock Index (S&P 500) for the period from December 31, 2010 through December 31, 2015. The comparison assumes that $100 was invested on December 31, 2010 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.

	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
Regeneron	$100.00	$168.84	$521.08	$838.38	$1,249.62	$1,653.58
S&P 500	100.00	100.00	113.40	146.97	163.71	162.52
NQ US Pharma TR Index	100.00	117.48	134.31	182.23	221.99	234.05

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 2015, we settled the conversion of $166.5 million principal amount of our 1.875% convertible senior notes through the payment of $166.5 million in cash (equal to the principal amount of the converted Notes) and issuance of 1,625,113 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 these conversions, we exercised a proportionate amount of our convertible note hedges, as a result of which we received from our hedge counterparties an aggregate of 1,625,088 shares of our Common Stock.

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Issuer Purchases of Equity Securities

The following table reflects shares of Common Stock withheld by us in the fourth quarter of 2015 for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan or the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
12/1/2015-12/31/2015	5,327	$544.35	—	—

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Item 6. Selected Financial Data

The selected financial data set forth below for the years ended December 31, 2015, 2014, and 2013 and as of December 31, 2015 and 2014 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, 2012 and 2011 and as of December 31, 2013, 2012, and 2011 are derived from our audited financial statements not included in this report. Certain revisions have been made to the previously reported amounts in each of the periods presented below, including revisions related to our accounting for certain stock option awards; see Note 1 and Note 14 to our Consolidated Financial Statements for further details.

	Year Ended December 31,				
(In thousands, except per share data)	2015	2014	2013	2012	2011
Statement of Operations Data:					
Revenues:					
Net product sales	$2,689,478	$1,750,762	$1,425,839	$858,093	$44,686
Collaboration revenue	1,339,361	1,036,854	650,400	493,913	369,681
Other revenue	74,889	31,941	28,506	26,471	31,457
	4,103,728	2,819,557	2,104,745	1,378,477	445,824
Expenses:					
Research and development	1,620,577	1,271,353	859,947	625,554	529,506
Selling, general, and administrative	838,526	519,267	346,393	229,859	119,361
Cost of goods sold	241,702	129,030	118,048	83,927	4,216
Cost of collaboration and contract manufacturing	151,007	75,988	37,307	528	—
	2,851,812	1,995,638	1,361,695	939,868	653,083
Income (loss) from operations	1,251,916	823,919	743,050	438,609	(207,259)
Other income (expense)	(26,819)	(62,684)	(46,668)	(43,292)	(17,733)
Income (loss) before income taxes	1,225,097	761,235	696,382	395,317	(224,992)
Income tax (expense) benefit [1]	(589,041)	(423,109)	(282,644)	347,081	1,132
Net income (loss)	$636,056	$338,126	$413,738	$742,398	$(223,860)
Net income (loss) per share - basic	$6.17	$3.36	$4.23	$7.84	$(2.47)
Net income (loss) per share - diluted	$5.52	$2.98	$3.72	$6.69	$(2.47)

	As of December 31,				
(In thousands)	2015	2014	2013	2012	2011
Balance Sheet Data:					
Unrestricted and restricted cash, cash equivalents, and marketable securities (current and non-current)	$1,677,385	$1,360,634	$1,083,875	$587,511	$810,550
Total assets	5,609,132	3,837,672	2,950,130	2,091,723	1,323,583
Convertible senior notes (current and non-current)	10,802	146,773	320,315	296,518	275,019
Facility lease obligations (current and non-current)	364,708	312,291	185,197	160,810	160,514
	—	—	126	1,309	2,506

Capital lease obligations (current and non-current)					
Stockholders' equity	3,654,837	2,550,251	1,964,716	1,256,618	485,732

(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.

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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, high LDL cholesterol, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including oncology, RA, asthma, atopic dermatitis, pain, and infectious diseases.

As described in Part I, Item 1. "Business - General," and "Business - Marketed Products," we currently have three marketed products: EYLEA (aflibercept) Injection, Praluent (alirocumab) Injection, and ARCALYST (rilonacept) Injection for Subcutaneous Use. We also have 13 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 12 fully human monoclonal antibody product candidates, as summarized in Part I, Item 1. "Business - General."

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 2015 and 2016 to date were, and plans for the remainder of 2016 are, as follows:

Trap-based Clinical Program:

	2015 and 2016 Events to Date	2016 Plans
EYLEA	Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD, macular edema secondary to CRVO, and DME, and continued to pursue regulatory applications for marketing approval in additional countries	Bayer HealthCare to file for additional regulatory approvals outside the United States for various indications Regulatory agency decisions on applications outside the United States for various indications
	European Commission and Japanese MHLW approved EYLEA for the treatment of macular edema secondary to BRVO	Initiate Phase 3 study for the treatment of diabetic retinopathy in patients without DME
	FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME	
	Initiated Phase 3 trial for NVG in Japan	
	European Commission approved EYLEA for the treatment of mCNV	

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Antibody-based Clinical Programs:

	2015 and 2016 Events to Date	2016 Plans
Praluent (PCSK9 Antibody)	BLA accepted for priority review in the United States	Report additional results from Phase 3 ODYSSEY trials
	Regulatory application accepted for review by the EMA	File for additional regulatory approvals outside the United States
	Reported positive results from ODYSSEY CHOICE I and CHOICE II trials	Regulatory agency and reimbursement authority decisions on applications outside the United States
	ODYSSEY LONG TERM 18-month trial results published in The New England Journal of Medicine	Prespecified early-stopping interim analyses by IDMC of ODYSSEY OUTCOMES trial
	Reported positive results from ODYSSEY Japan trial	Submit supplemental BLA for monthly dosing regimen
	FDA approved Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol	
	European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia	
	Completed patient enrollment in Phase 3 ODYSSEY OUTCOMES trial	
Sarilumab (IL-6R Antibody)	Initiated and completed patient enrollment in Phase 3 SARIL-RA-MONARCH study (head-to-head monotherapy study against adalimumab)	Continue patient enrollment in Phase 3 SARIL-RA program
		Report results from Phase 3 SARIL-RA-MONARCH trial
	Initiated several studies in Japan	Regulatory agency decision on application for U.S. approval
	Reported positive results from SARIL-RA-TARGET, SARIL-RA-EASY, and SARIL-RA-ASCERTAIN trials	File for regulatory approvals outside the United States
	Completed patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis and reported top-line results	
	BLA accepted for review in the United States	
Dupilumab (IL-4R Antibody)	Initiated Phase 2 study in EoE	Continue patient enrollment in various Phase 2 and Phase 3 studies
	Initiated and completed enrollment for Phase 2 study in atopic dermatitis in pediatric patients	Complete patient enrollment in Phase 2 EoE and Phase 3 asthma studies

	Initiated Phase 3 study in asthma Presented positive pivotal Phase 2b data in asthma at the American Thoracic Society 2015 International Conference Completed patient enrollment in Phase 3 atopic dermatitis pivotal trials FDA granted Breakthrough Therapy designation to dupilumab in atopic dermatitis UK MHRA granted PIM Designation to dupilumab in atopic dermatitis	Report results from Phase 3 atopic dermatitis pivotal trials Complete rolling BLA submission for atopic dermatitis in the United States Initiate efficacy and safety studies in pediatric patients in both atopic dermatitis and asthma

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Antibody-based Clinical Programs (continued):

	2015 and 2016 Events to Date	2016 Plans
REGN2222 (RSV-F Antibody)	Completed Phase 1 study Initiated Phase 3 NURSERY Pre-Term study Received Fast Track designation from the FDA for the prevention of serious lower respiratory tract disease caused by RSV	Continue patient enrollment in Phase 3 NURSERY Pre-Term study
Fasinumab (NGF Antibody)	Initiated sixteen-week Phase 2b/3 study in osteoarthritis Completed patient enrollment in a Phase 2b/3 study in osteoarthritis	Report results from Phase 2b/3 study in osteoarthritis Initiate longer duration Phase 3 trial
Evinacumab (Angptl-3 Antibody)	Initiated Phase 2 study	Complete patient enrollment in Phase 1 and Phase 2 studies
REGN1033 (GDF8 Antibody)	Partial clinical hold lifted by the FDA Phase 2 proof-of-concept study in elderly men and women with sarcopenia met its primary endpoint, while secondary, functional endpoints were mixed. Sanofi elected not to continue co-development	Develop combination therapy plans
REGN1908-1909 (Feld1 Antibody)	Completed patient enrollment in Phase 1/Phase 2 study	
REGN2176-3 (PDGFR-beta Antibody co-formulated with aflibercept)	Received Fast Track designation from the FDA for the treatment of patients with wet AMD Initiated Phase 2 study	Continue patient enrollment in Phase 2 study
REGN1979 (CD20 and CD3 Antibody)	Continued patient enrollment in Phase 1 study	Complete patient enrollment in Phase 1 study
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	Completed patient enrollment in Phase 1 study	Initiate Phase 2 study
REGN2810 (PD-1 Antibody)	Initiated Phase 1 study	Continue patient enrollment in Phase 1 study Initiate later-stage pivotal studies

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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, are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of Praluent and preparation for potential commercialization of our late-stage antibody product candidates, approximately half of which we expect to be reimbursed by Sanofi under the companies' collaboration agreement. Our financial 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, the continuation of our collaborations, in particular 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, and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for 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.

Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 1 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 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.

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(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
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
Provision related to current period sales	61.1	122.5	9.6	193.2
Credits/payments	(57.8)	(95.3)	(9.6)	(162.7)
Balance as of December 31, 2015	$6.4	$48.4	$0.5	$55.3

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 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.

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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.

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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.

Uncertain tax 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 recognition and measurement criteria. Significant judgment is required in making this assessment, and therefore, we re-evaluate uncertain tax positions and consider various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain positions.

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 2015, 2014, and 2013, cost of goods sold included inventory write-downs and reserves totaling $10.6 million, $6.0 million, and $9.1 million, respectively.

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Results of Operations

The results of operations discussion below reflects certain revisions to previously-issued financial statements. See Note 1 of the Notes to Consolidated Financial Statements for a description of such revisions.

Years Ended December 31, 2015 and 2014

Net Income

Net income in 2015 and 2014 consists of the following:

(In millions)	2015	2014
Revenues	$4,103.7	$2,819.6
Operating expenses	(2,851.8)	(1,995.6)
Other income (expense)	(26.8)	(62.7)
Income before income taxes	1,225.1	761.3
Income tax expense	(589.0)	(423.1)
Net income	$636.1	$338.2
Net income per share - diluted	$5.52	$2.98

Revenues

Revenues in 2015 and 2014 consist of the following:

(In millions)	2015	2014
Net product sales	$2,689.5	$1,750.8
Collaboration revenue:		
Sanofi	758.9	541.3
Bayer HealthCare	580.5	495.6
Total collaboration revenue	1,339.4	1,036.9
Other revenue	74.8	31.9
Total revenues	$4,103.7	$2,819.6

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 2011, macular edema following CRVO in 2012, DME in July 2014, macular edema following BRVO in October 2014, and diabetic retinopathy in patients with DME in March 2015. In 2015, EYLEA net product sales increased to $2,676.0 million from $1,736.4 million in 2014 due to higher sales volume. In 2015 and 2014, we also recognized ARCALYST net product sales of $13.5 million and $14.4 million, respectively.

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, primarily consisted of reimbursement for research and development and commercialization expenses that we incurred, partly offset by sharing of losses in connection with commercialization of antibodies, under the companies' Antibody Collaboration.

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Sanofi Collaboration Revenue	Year Ended December 31,	
(In millions)	2015	2014
Antibody:		
Reimbursement of Regeneron research and development expenses	$735.4	$547.8
Reimbursement of Regeneron commercialization-related expenses	157.4	19.5
Regeneron's share of losses in connection with commercialization of antibodies	(240.0)	(41.4)
Other	10.2	10.2
Total Antibody	663.0	536.1
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	40.0	—
Other	40.0	—
Total Immuno-oncology	80.0	—
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	(4.7)
Reimbursement of Regeneron research and development expenses	0.7	4.8
Other	15.2	5.1
Total ZALTRAP	15.9	5.2
Total Sanofi collaboration revenue	$758.9	$541.3

In 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of $145.0 million under our Antibody Discovery Agreement and $590.4 million under our License and Collaboration Agreement, compared to $160.0 million and $387.8 million, respectively, in 2014. Under the amended Antibody Discovery Agreement, Sanofi agreed to fund our antibody discovery activities up to $145.0 million in 2015 and up to $160.0 million in 2014. The higher reimbursement of development costs in 2015 compared to 2014 was primarily due to increased development activities for dupilumab.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent and sarilumab. Effective in the second and fourth quarters of 2014, we and Sanofi began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement. Consequently, we began recording our share of losses in connection with preparing to commercialize these two antibodies within Sanofi collaboration revenue. As described in Item 1. "Business" above, in July 2015, the FDA approved Praluent in the United States and in September 2015, the European Commission granted marketing authorization of Praluent. Therefore, commencing in 2015, we also recorded within Sanofi collaboration revenue our share of the Antibody Collaboration's losses in connection with commercialization of Praluent. We and Sanofi incurred higher commercialization expenses for Praluent in 2015 primarily in connection with launching the product in the United States. Praluent net product sales, which are recorded by Sanofi, were $10.5 million in 2015.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of December 31, 2015, $64.2 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (as described above under "Collaboration Agreements - Collaboration with Sanofi - Immuno-Oncology"). In 2015, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $29.2 million under our IO Discovery Agreement and $10.8 million under our IO License and Collaboration Agreement.

Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements. As of December 31, 2015, $600.0 million of the up-front payments was deferred and will be recognized ratably as

revenue in future periods.

In September 2003, we and Sanofi entered into a ZALTRAP Collaboration Agreement to jointly develop and commercialize ZALTRAP. Under the terms of the ZALTRAP Collaboration Agreement, we and Sanofi shared profits and losses on sales of

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ZALTRAP outside of Japan, and we were entitled to receive a percentage of sales of ZALTRAP in Japan. Our share of the loss in connection with the commercialization of ZALTRAP in 2014 represents our share of the costs of commercializing ZALTRAP, partly offset by net product sales. As described above in Part I, Item 1. "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP", in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement. As a result, in the first quarter of 2015 we recognized $14.9 million of previously deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since our risk of inventory loss under the collaboration no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as we had no further performance obligations.

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 milestones achieved.

Bayer HealthCare Collaboration Revenue	Year Ended December 31,	
(In millions)	2015	2014
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$466.7	$301.3
Sales milestones	15.0	105.0
Cost-sharing of Regeneron EYLEA development expenses	8.9	23.4
Other	69.4	52.4
Total EYLEA	560.0	482.1
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	10.1	2.9
Other	10.4	10.6
Total PDGFR-beta antibody	20.5	13.5
Total Bayer HealthCare collaboration revenue	$580.5	$495.6

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME in the third quarter of 2014, mCNV (in Japan) in the fourth quarter of 2014, and macular edema following BRVO in the second quarter of 2015. 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)	2015	2014
Net product sales outside the United States	$1,413.3	$1,038.5
Regeneron's share of collaboration profit from sales outside the United States	521.8	358.3
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(55.1)	(57.0)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$466.7	$301.3

Bayer HealthCare records revenue from sales of EYLEA outside the United States. In 2015 and 2014, 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.

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In 2015, we earned our final $15.0 million sales milestone from Bayer HealthCare, upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. In 2014, we earned seven $15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States achieving certain specified levels.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in 2015 compared to 2014. 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 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 are also shared (for countries other than Japan; we are entitled to receive a tiered percentage of EYLEA net sales in Japan).

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States and reimbursements for producing EYLEA commercial supplies for Bayer HealthCare. In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of December 31, 2015, $11.1 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. 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, 2015, $9.5 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

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 2015 and 2014, we recognized $23.6 million of revenue related to this agreement. As of December 31, 2015, $57.4 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

In connection with the February 2015 Amended ZALTRAP Agreement with Sanofi, we recorded $38.8 million of revenue in 2015 primarily related to manufacturing ZALTRAP commercial supplies for Sanofi and a percentage of net sales of ZALTRAP from July 1, 2014 (the effective date of the Amended ZALTRAP Agreement) through December 31, 2015, which Sanofi is obligated to pay us.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris (canakinumab). In 2015 and 2014, other revenue included $8.9 million and $7.9 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $2,851.8 million in 2015 from $1,995.6 million in 2014. Our average headcount in 2015 increased to 3,713 from 2,629 in 2014, principally in connection with expanding our research and development, and commercialization activities.

Operating expenses in 2015 and 2014 included a total of $459.0 million and $321.8 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 2015 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 2014 compared to recent prior years. As of December 31, 2015, unrecognized Non-cash Compensation Expense related to outstanding stock options was $962.6 million and unvested restricted stock awards was $33.9 million. We expect to

recognize this Non-cash Compensation Expense over weighted-average periods of 2.0 years and 2.1 years, respectively.

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Research and Development Expenses

Research and development expenses increased to $1,620.6 million in 2015 from $1,271.4 million in 2014. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses (In millions)	Year Ended December 31, 2015	2014	Increase (Decrease)
Payroll and benefits [1]	$506.3	$401.6	$104.7
Clinical trial expenses	306.1	203.0	103.1
Clinical manufacturing costs [2]	431.8	284.8	147.0
Research and other development costs	133.6	137.2	(3.6)
Occupancy and other operating costs	136.4	116.5	19.9
Cost-sharing of Bayer HealthCare and Sanofi development expenses [3]	106.4	128.3	(21.9)
Total research and development expenses	$1,620.6	$1,271.4	$349.2

[1] Includes Non-cash Compensation Expense of $216.6 million in 2015 and $157.1 million in 2014.

[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 $39.1 million in 2015 and $27.2 million in 2014.

[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's 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 primarily due to additional costs for clinical studies of dupilumab and fasinumab, partly offset by lower Praluent, EYLEA, and REGN1033 costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of dupilumab and, to a lesser extent, other late-stage antibody product candidates. Research and other development costs decreased primarily due to our 50% share ($33.8 million) of the cost of purchasing an FDA priority review voucher in 2014, partly offset by an increase in lab supplies in connection with early stage research activities. 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 decreased primarily due to lower development costs incurred by Bayer HealthCare in connection with EYLEA and Sanofi in connection with sarilumab.

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We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer HealthCare and Sanofi, the portion of Bayer HealthCare's and Sanofi's respective 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)	2015	2014	(Decrease)
Praluent	$231.0	$316.4	$(85.4)
Dupilumab	404.0	169.0	235.0
Sarilumab	84.6	86.1	(1.5)
EYLEA	75.0	110.4	(35.4)
Fasinumab	56.1	8.2	47.9
REGN2222	42.6	16.7	25.9
Other antibody candidates in clinical development	185.8	171.6	14.2
Other research programs and unallocated costs	541.5	393.0	148.5
Total research and development expenses	$1,620.6	$1,271.4	$349.2

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3b and 4 studies. Phase 3b studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product.

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

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

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $838.5 million in 2015 from $519.3 million in 2014 primarily due to higher headcount and headcount-related costs, higher non-cash Compensation Expense principally for the reason described under "Expenses" above, and higher commercialization-related expenses primarily associated

with EYLEA and Praluent. Selling, general, and administrative expenses included $193.0 million and $134.7 million of Non-cash Compensation Expense in 2015 and 2014, respectively.

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Selling, general and administrative expenses in 2014 included a $40.6 million incremental charge related to the Branded Prescription Drug Fee, which is a non-tax deductible annual fee imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. In July 2014, the Internal Revenue Service (IRS) issued final regulations that provide guidance on the Branded Prescription Drug Fee. As a result of the issuance of these final IRS regulations, 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. The impact of the 2014 incremental charge was offset by a higher Branded Prescription Drug Fee expense in 2015 due to higher sales of EYLEA in the United States.

Cost of Goods Sold

Cost of goods sold was $241.7 million in 2015 and $129.0 million in 2014. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold increased principally due to the increase in U.S. EYLEA net sales, as well as an increase in Limerick start-up costs. In addition, in 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $10.6 million and $6.0 million, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer HealthCare, increased to $151.0 million in 2015 from $76.0 million in 2014. This increase was primarily due to the recognition of costs associated with commercial supplies of ZALTRAP, as well as royalties payable to Genentech in connection with higher sales of EYLEA outside the United States and the recognition of costs associated with commercial supplies of EYLEA manufactured for Bayer HealthCare. Under our collaboration arrangements, when the product is sold by our collaborators to third-party customers, our risk of inventory loss no longer exists, and we therefore recognize our related manufacturing costs for the sold product as cost of collaboration manufacturing. However, as described above, in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi. As a result, in the first quarter of 2015 we recognized as expense $20.2 million of inventoried costs for ZALTRAP commercial supplies that were previously shipped to Sanofi because our risk of inventory loss no longer exists under the Amended ZALTRAP Agreement.

Other Income and Expense

Total other expenses (net of other income) decreased to $26.8 million in 2015 from $62.7 million in 2014. Interest expense in 2015 decreased compared to 2014 primarily due to conversions of a substantial portion of our Notes in 2014 and 2015. In addition, in 2015 and 2014, we recognized a $18.9 million and a $33.5 million non-cash charge, respectively, in connection with Notes which were surrendered for conversion during the respective periods.

Income Taxes

In 2015, we recorded income tax expense of $589.0 million, based on an effective tax rate of 48.1%. The 2015 effective tax rate was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, partly offset by the positive impact of the domestic manufacturing deduction.

In 2014, we recorded income tax expense of $423.1 million, based on an effective tax rate of 55.6%. The 2014 effective tax rate was negatively impacted, compared to the U.S. federal statutory rate, 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. The negative impact of these items was partly offset by the positive impact of the federal tax credit for increased research activities and state income state credits.

We expect our effective tax rate to continue to be negatively impacted by a shift in our geographic mix of profits and losses in 2016.

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Years Ended December 31, 2014 and 2013

The results of operations discussion below reflects certain revisions to previously-issued financial statements. See Note 1 of the Notes to Consolidated Financial Statements for a description of such revisions.

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	(1,995.6)	(1,361.7)
Other income (expense)	(62.7)	(46.6)
Income before income taxes	761.3	696.4
Income tax expense	(423.1)	(282.6)
Net income	$338.2	$413.8
Net income per share - diluted	$2.98	$3.72

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
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.

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.

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Sanofi Collaboration Revenue

(In millions)	Year Ended December 31, 2014	2013
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
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)
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

(In millions)	Year Ended December 31, 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 ZALTRAP 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 Antibody Discovery Agreement and $387.8 million under our License and Collaboration Agreement, compared to $160.0 million and $293.5 million, respectively, in 2013. Under the amended Antibody Discovery Agreement, Sanofi agreed to fund up to $160.0 million of our antibody discovery activities in 2014 and 2013. 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.

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 ophthalmology 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.

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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, 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

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

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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. 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 a license and settlement agreement, 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.

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. 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.

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 other revenue related to this agreement.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris. In 2014 and 2013, other revenue included $7.9 million and $4.8 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $1,995.6 million in 2014 from $1,361.7 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 $321.8 million and $215.4 million, respectively, of 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.

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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

[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's 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 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.

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We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our 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

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $519.3 million in 2014 from $346.4 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, as described above under "Results of Operations - Years Ended December 31, 2015 and 2014 - Selling, General, and Administrative Expenses."

Selling, general, and administrative expenses included $134.7 million and $97.0 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 a license and settlement agreement, 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 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 Notes which were surrendered for conversion during 2014. In addition, in 2014, we recognized a $33.5 million non-cash charge in connection with these conversions.

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Income Taxes

In 2014, we recorded income tax expense of $423.1 million, based on an effective tax rate of 55.6%. The 2014 effective tax rate was negatively impacted, compared to the U.S. federal statutory rate, 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. 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. The negative impact of these items was partly offset by the positive impact of the federal tax credit for increased research activities and state income tax credits.

In 2013, we recorded income tax expense of $282.6 million, based on an effective tax rate of 40.6%. 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.

Liquidity and Capital Resources

The sources and uses of cash discussion below reflects certain revisions to previously-issued financial statements. See Note 1 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

Sources and Uses of Cash for the Years Ended December 31, 2015, 2014, and 2013

As of December 31, 2015, we had $1,677.4 million in cash, cash equivalents, and marketable securities compared with $1,360.6 million as of December 31, 2014 and $1,083.9 million as of December 31, 2013. Additionally, as of December 31, 2015, we had borrowing availability of $750.0 million under a revolving credit facility that was entered into during the first quarter of 2015 (see further description under "Credit Facility" below).

Cash Provided by Operating Activities

2015. Net cash provided by operating activities was $1,330.8 million in 2015. Our net income of $636.1 million in 2015 included Non-cash Compensation Expense of $459.0 million and depreciation and amortization of $74.9 million. In addition, deferred tax assets as of December 31, 2015 increased by $121.6 million, compared to December 31, 2014, primarily due to an increase in Non-cash Compensation Expense, partly offset by a reduction in our deferred tax assets related to fixed assets and deferred revenue.

As of December 31, 2015, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $491.4 million, compared to December 31, 2014, primarily due to higher U.S. EYLEA sales. Inventories as of December 31, 2015 increased by $111.8 million, compared to December 31, 2014, primarily due to increased production of EYLEA commercial supplies as well as capitalization of inventory in connection with Praluent production. Prepaid expenses and other assets increased by $79.5 million as of December 31, 2015, compared to December 31, 2014, primarily due to an increase in prepaid income taxes. Deferred revenue increased by $608.9 million as of December 31, 2015, compared to December 31, 2014, primarily due to $640.0 million of up-front payments received from Sanofi in connection with the companies' IO Collaboration, partly offset by related amortization which commenced in the third quarter of 2015. Accounts payable, accrued expenses, and other liabilities increased by $303.7 million as of December 31, 2015, compared to December 31, 2014, primarily due to (i) higher accruals for sales-related charges and deductions, and royalties related to EYLEA, (ii) higher expenditures in connection with our expanding research and development activities, (iii) higher payroll and payroll-related costs, and (iv) higher tax-related liabilities.

2014. Net cash provided by operating activities was $752.4 million in 2014. Our net income of $338.1 million in 2014 included the following non-cash expenses: (i) Non-cash Compensation Expense of $321.8 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 Notes during 2014. In addition, deferred tax assets as of December 31, 2014 increased by $53.3 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 $34.9 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 $56.9 million, compared to end-of-year

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2013, primarily in connection with increased production of EYLEA commercial supplies. Accounts payable, accrued expenses, and other liabilities increased by $161.2 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 $588.6 million in 2013. Our net income of $413.7 million in 2013 included Non-cash Compensation Expense of $215.4 million and depreciation and amortization of $41.2 million. In addition, deferred tax assets at December 31, 2013 decreased by $62.2 million, compared to end-of-year 2012, primarily due to utilization of net operating loss and tax credit carryforwards to offset income taxes payable during 2013.

As of December 31, 2013, Sanofi, Bayer HealthCare, and trade accounts receivable increased by $245.5 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 $41.5 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. 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.

Cash Used in Investing Activities

Net cash used in investing activities was $907.6 million, $420.8 million, and $355.5 million in 2015, 2014, and 2013, respectively. In 2015, 2014, and 2013, purchases of marketable securities exceeded sales or maturities by $229.7 million, $87.8 million, and $199.1 million, respectively. Capital expenditures were $677.9 million, $333.0 million, and $156.3 million in 2015, 2014, and 2013, respectively. Capital expenditures in 2015 included costs in connection with renovations of our Limerick, Ireland manufacturing facility, tenant improvement and associated costs related to two new buildings at our leased Tarrytown, New York facilities, and expansion of our Rensselaer, New York manufacturing facilities. In addition, in April 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our current Tarrytown, New York location for an aggregate purchase price of $73.0 million. We intend to develop this property to accommodate and support our growth, primarily in connection with expanding our existing research and development and office space. Capital expenditures in 2014 and 2013 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 $262.8 million and $218.5 million in 2015 and 2014, respectively, and net cash provided by financing activities was $72.2 million in 2013. In 2015, proceeds in connection with facility and capital lease obligations primarily relate to reimbursements of $27.4 million from our landlord for tenant improvement costs in connection with our leased facilities in Tarrytown, New York. In 2015 and 2014, $166.5 million and $220.6 million principal amount of our Notes, respectively, that was previously surrendered for conversion was settled. 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 2015 and 2014, we paid an aggregate amount of $573.5 million and $294.6 million, respectively, to 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 $206.4 million in 2015 compared to $126.0 million in 2014 and $57.4 million in 2013. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted stock were $160.5 million in 2015 compared to $267.6 million in 2014 and $195.1 million in 2013. Cash flows from financing activities also increased by $405.3 million, $439.3 million, and $211.9 million in 2015, 2014, and 2013, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

Credit Facility

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a $750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the

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aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of December 31, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Credit Facility as of December 31, 2015.

Collaborations with Sanofi

Antibodies

As described above under Item 1. "Business - Collaboration Agreements - Collaborations 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. Pursuant to the Antibody Collaboration, Sanofi was responsible for funding up to $160.0 million per year of our antibody discovery activities over the period from 2010-2014, and, as amended in connection with the companies' July 2015 IO Collaboration as described below, is responsible for funding up to $145.0 million in 2015, and up to $130.0 million in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. For each drug candidate identified through discovery research under the Antibody Discovery Agreement, Sanofi has the option to license rights to the candidate under the License and Collaboration Agreement. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10.0 million substantive milestone payment to us.

Under the License and Collaboration 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, we recognized as additional research and development expense $92.6 million, $109.7 million, and $17.6 million in 2015, 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. Our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately $1,832 million as of December 31, 2015. If Sanofi does not exercise its option to license rights to a particular drug candidate under the License and Collaboration agreement, or, if Sanofi elects not to continue to co-develop the product candidate, we retain the exclusive right to develop and commercialize such drug candidate, and Sanofi will receive either a mid-single digit or 10% royalty on sales, if any. See Item 1. "Business - General," above for product candidates that are subject to potential future royalties.

As it relates to commercialization activities, we and Sanofi equally share profits and losses within the United States. We and Sanofi 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 share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250.0 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.

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. During 2014, Sanofi

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

With respect to each antibody product which enters development under the License and Collaboration 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 and Collaboration Agreement. Each of the Antibody Discovery Agreement and the License and Collaboration 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 Discovery Agreement without cause with at least

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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 Antibody Collaboration in its entirety, our obligation to reimburse Sanofi for development costs out of any future profits from collaboration products will terminate. In the event of termination of the amended Antibody Discovery Agreement, we retain exclusive rights to continue the development and/or commercialization of such product(s).

Immuno-Oncology

As described above under Item 1. "Business - Collaboration Agreements - Collaborations with Sanofi," in July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology. The IO Collaboration is governed by an IO Discovery Agreement and an IO License and Collaboration Agreement. In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million of these costs, subject to certain annual limits (including an annual limit of $150.0 million in 2016), to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized 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 IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured. Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, we or Sanofi may, by giving twelve months’ notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

Collaborations with Bayer HealthCare

EYLEA outside the United States

As described above under Item 1. "Business - Collaboration Agreements - Collaborations 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.

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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 a portion of our share of 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 $258 million as of December 31, 2015. We are obligated to use commercially reasonable efforts to supply clinical and commercial bulk product of EYLEA to Bayer HealthCare.

Since inception of the agreement, we have earned $110.0 million of development milestones and $165.0 million of sales milestones from Bayer HealthCare. During the first quarter of 2015, we earned the final potential milestone payment under our Bayer HealthCare collaboration agreement in connection with EYLEA outside the United States. 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. We recognized as additional research and development expense $13.7 million, $18.6 million, and $15.3 million in 2015, 2014, and 2013, respectively, of EYLEA development expenses that we were obligated to reimburse to Bayer HealthCare related to EYLEA development costs.

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

As described above under Item 1. "Business - Collaboration Agreements - Collaborations with Bayer HealthCare," 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 aflibercept, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept, 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 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 2014 and a $5.0 million development milestone payment to us in 2015. We are eligible to receive up to a $10.0 million additional future development milestone payment from Bayer HealthCare, although this payment 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 EU 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.

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 aflibercept) 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.

Fasinumab Collaboration with Mitsubishi Tanabe Pharma

As described above under Item 1. "Business - Collaboration Agreements - Collaborations with Mitsubishi Tanabe Pharma," in September 2015, we and MTPC entered into a collaboration agreement providing MTPC with development and commercial

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rights to fasinumab in Japan and certain other countries in Asia. In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment to us in 2015, and in the first quarter of 2016, MTPC became obligated to make an additional $45.0 million payment to us. We are also entitled to receive up to an aggregate of $65.0 million in development milestones if achieved by us and $105.0 million in other contingent payments, primarily related to development milestones achieved by MTPC.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

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.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (which 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, 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 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. As a result of the Amended ZALTRAP Agreement, which is described in Item 1. "Business" above, we are no longer required to share in the cost of any payments made by Sanofi to Genentech based on sales of ZALTRAP.

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Tarrytown, New York Leases

We lease approximately 1,108,000 square feet of laboratory and office space at facilities in Tarrytown, New York. In 2013, we entered into a lease agreement for approximately 297,000 square feet of laboratory and office space to be constructed in two new buildings, which were completed in 2015. Our Tarrytown leases expire in 2024 - 2029, but contain renewal options to extend the term of the leases, as well as early termination options on approximately 225,000 square feet of space. The Tarrytown leases provide for current monthly base rental charges of approximately $3,525,000 (subject to escalations at 2.5% per annum) and additional charges for utilities, real estate taxes, and operating expenses, as defined.

Certain leased premises are accounted for as operating leases. However, for certain other buildings that we are leasing (related to approximately 660,000 square feet), we are deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of Financial Accounting Standards Board (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, 2015 and 2014, the facility lease obligation balance related to these buildings was $364.7 million and $312.3 million, respectively.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $677.9 million in 2015, $333.0 million in 2014, and $156.3 million in 2013 (as described under "Cash Used in Investing Activities" above). We expect to incur capital expenditures of approximately $580 million to $680 million in 2016 primarily in connection with renovating our new Limerick, Ireland facility, tenant improvements primarily related to buildings at our leased Tarrytown, New York facilities, and expanding and renovating a portion of our manufacturing facilities at our Rensselaer, New York facility.

Convertible Senior Notes

In October 2011, we issued $400.0 million aggregate principal amount of 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 (which can occur subject to certain conditions) 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 Notes initial conversion price is approximately $84.02 per share. 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 initial offering of the Notes, we entered into convertible note hedge (call option) and warrant transactions with multiple counterparties. The convertible note hedge covers, 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 warrants 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 2015, we settled conversion obligations for $166.5 million principal amount of Notes previously 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 respect of any amounts due in excess thereof. As a result of the settlement of the Notes, we exercised a proportionate amount of our convertible note hedges, for which we received shares of Common Stock, which was approximately equal to the number of shares we were required to issue to settle the non-cash portion of the related Note conversions.

In November 2015, we entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 476,376. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder

closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $535.00 per share, during the period starting on November 16, 2015 and ending no later than February 9, 2016. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2015, we paid a total of $50.0 million in 2015 to reduce the number of warrants held by such warrant holder by 115,970. Additionally, during January 2016, the warrant holder closed out additional portions of its hedge position, and, as a result, we paid $135.3 million to further reduce the number of warrants held by such warrant holder by 360,406 (which was the remaining maximum number of warrants to be reduced subject to the amendment agreement).

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In addition to cash paid pursuant to the November 2015 agreement noted above, during 2015 we paid an aggregate amount of $523.5 million to warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. As of December 31, 2015, an aggregate of 2,109,098 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

Funding Requirements

We expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), costs related to the preparation for potential commercialization of our late-stage antibody product candidates, and commercialization of EYLEA and Praluent. We believe that our existing capital resources, borrowing availability under our revolving credit facility, funds generated by anticipated EYLEA net product sales, and, as described above under "Collaboration Agreements," funding for reimbursement of research and development costs that we are entitled to receive under our collaboration agreements with Sanofi and Bayer HealthCare, will enable us to meet our projected operating needs for the foreseeable future.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2015. 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]	$11.4	$11.4	—	—	—
Operating leases [2]	112.8	15.5	$23.5	$23.1	$50.7
Purchase and other obligations [3]	1,066.8	585.9	431.4	32.5	17.0
Facility lease obligations [4]	472.4	31.2	64.6	67.7	308.9
Total contractual obligations	$1,663.4	$644.0	$519.5	$123.3	$376.6

(1) Consists of $11.2 million remaining aggregate principal amount of 1.875% convertible senior notes that mature on October 1, 2016, unless earlier converted or repurchased. The amount in the table above assumes the payment of interest on our 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 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 11 to our Consolidated Financial Statements.

(2) Excludes future contingent costs for utilities, real estate taxes, and operating expenses. In 2015, these costs were $15.5 million. See Note 12(a) to our Consolidated Financial Statements.

(3) Purchase and other obligations primarily relate to research and development commitments, including those related to clinical trials, and capital expenditures for equipment acquisitions. 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 rent payments with respect to facility lease obligations in connection with our lease of certain buildings in Tarrytown, New York, as described under "Tarrytown, New York Leases" above. Rent payments on two of these buildings commenced in the second half of 2015, and were based on several factors, including the landlord's costs of construction and tenant allowances. See Note 12(a) to our Consolidated Financial Statements.

Liabilities for unrecognized tax benefits, totaling $116.6 million at December 31, 2015, 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 16 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. For example, in May 2013, we acquired from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications; consequently, we are obligated to pay up to $20.0 million in potential additional development milestones as well as royalties on any future sales of PDGF antibodies. 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

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specific timing cannot be predicted. Because of these factors, such payments are not included in the table of contractual obligations above. See Note 3 and Note 12 to our Consolidated Financial Statements.

Under our Antibody Collaboration with Sanofi and our collaboration with Bayer HealthCare for EYLEA outside the United States, we and our collaborator 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 Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses funded by Sanofi and Bayer HealthCare. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for 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, 2015, our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $258 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately $1,832 million. Therefore, we expect that, for the foreseeable future, a portion of our share of profits from sales of EYLEA outside the United States and a portion of our share of profits, if any, from sales of Praluent and other antibody product candidates (if approved) developed as part of the Antibody Collaboration will be used to reimburse our collaborator for this obligation. As described above under Item 1. "Business - Collaboration Agreements - Collaborations with Sanofi", pursuant to the Amended ZALTRAP Agreement, Regeneron no longer has a contingent contractual obligation (which was approximately $461 million at December 31, 2014) to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement.

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 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 (in particular those 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.

In addition to our anticipated commercialization costs for EYLEA and Praluent, we anticipate incurring substantial commercialization costs in connection with our late-stage antibody product candidates. Commercialization costs over the next few years will depend on, among other things, whether or not our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for 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 certain commercial products. In the future, if we are able to successfully develop, market, and sell 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 2015, 2014, and 2013, we made cash payments of $160.5 million, $267.6 million, and $195.1 million, respectively, for employee tax obligations in connection with stock option exercises and vesting of restricted stock. Future cash requirements for such payments will depend on various factors, including the level of stock option grants and exercises and the sales prices of our Common Stock, and may continue to be substantial.

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

As described under "Convertible Senior Notes" above, in November 2015, we entered into an agreement with a warrant holder whereby the parties agreed to reduce the number of warrants held by the warrant holder. Under the terms of the agreement, during 2015 and January 2016, we paid a total of $50.0 million and $135.3 million, respectively, to reduce the number of warrants held by the warrant holder. From time to time, we may seek to further reduce the number of warrants outstanding through additional amendment agreements with warrant holders or otherwise.

Due primarily to potential excess tax benefits in connection with stock option exercises, we expect our cash income tax payments for 2016 to be significantly less than the income tax expense recorded in our financial statements in 2016, which is based on an

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effective tax rate. However, we expect our cash income tax payments in 2016 to be substantially higher than such payments in 2015.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our consolidated financial position or results of operations.

Future Impact of Recently Issued Accounting Standards

In November 2015, the FASB issued Accounting Standards Update 2015-17, Balance Sheet Classification of Deferred Taxes, which is intended to simplify the balance sheet presentation of deferred income taxes. Current accounting principles require an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in its balance sheet. The amendments require that deferred tax liabilities and assets be classified as noncurrent in its balance sheet. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Companies may apply the new provisions either retrospectively or on a prospective basis, and early adoption is permitted. We early adopted the amendments effective December 31, 2015 on a retrospective basis. The impact of the adoption of the amendments on our Consolidated Balance Sheet as of December 31, 2014 was a $46.2 million reclassification of current deferred tax assets to noncurrent deferred tax assets.

In May 2014, the FASB issued Accounting Standards Update 2014-09, 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. In July 2015, the FASB decided to delay the effective date of the new standard by one year; as a result, the new standard will be effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption will be permitted, but no earlier than 2017 for calendar year-end entities. 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.

In January 2016, the FASB issued Accounting Standards Update 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments require equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and separate presentation of financial assets and financial liabilities by measurement category and form of financial asset. Additionally, the amendments eliminate the requirement to disclose the methods and significant assumptions used to estimate the fair value of financial instruments. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Other than an amendment relating to presenting in comprehensive income the portion of the total change in the fair value of a liability resulting from a change in instrument-specific credit risk (if the entity has elected to measure the liability at fair value), early adoption is not permitted. We 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 $11.7 million and $6.7 million decrease in the fair value of our investment portfolio as of December 31, 2015 and 2014, 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 2015 and 2014, 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.

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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 2015, 2014, and 2013, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. As of December 31, 2015 and 2014, one individual customer accounted for 68% and 70%, 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 Praluent worldwide, and we share in profits and losses with these collaborators from commercialization of products (including the receipt of a percentage of EYLEA sales in Japan). In addition, pursuant to the applicable terms of the agreements with our collaborators, we also share in certain worldwide development expenses incurred by our collaborators. We also incur worldwide development expenses for clinical products we are developing independently. Therefore, significant changes in foreign exchange rates of the countries outside the United States where our product is sold or where development expenses are incurred by us or 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-48 of this report. The supplementary financial information required by this Item is included at page F-48 of this report.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 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, 2015. The effectiveness of our internal control over financial reporting as of December 31, 2015 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.

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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, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2016 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 2016 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 2016 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 2016 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 2016 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.

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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	Restated Certificate of Incorporation, as amended. (Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. (the "Registrant"), for the quarter ended June 30, 2015, filed August 4, 2015.)
3.2	By-Laws, as amended.
4.1	Indenture, dated as of October 21, 2011, relating to 1.875% Convertible Senior Notes due October 1, 2016, between the Registrant and Wells Fargo Bank, National Association, as Trustee. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
4.2	Form of 1.875% Convertible Senior Note due October 1, 2016. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.1 +	Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 13, 2011.)
10.1.1 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed December 16, 2005.)
10.1.2 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed December 16, 2005.)
10.1.3 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed December 13, 2004.)
10.1.5 +	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. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.)
10.1.6 +	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. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.)
10.1.7 +	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). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2010, filed February 17, 2011.)
10.1.8 +	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). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31,

	2010, filed February 17, 2011.)
10.1.9 +	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). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2011, filed February 21, 2012.)
10.1.10 +	Amendment No. 1 to the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2013, filed February 13, 2014.)

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10.2 +	Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 16, 2014.)
10.2.1 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.2 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.3 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.4 +	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. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.5 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.2.6 +	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
10.2.7 +	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 (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.8 +	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 (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.9 +	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 (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.10 +	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 (revised).
10.3 +	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2008, filed February 26, 2009.)
10.4* +	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2004, filed March 11, 2005.)
10.5 +	Offer Letter for Robert E. Landry effective September 9, 2013. (Incorporated by reference from the Form 8-K for the Registrant, filed September 12, 2013.)
10.6 +	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008. (Incorporated by reference from the Form 10-K for the Registrant, for the year

	ended December 31, 2008, filed February 26, 2009.)
10.7 +	Regeneron Pharmaceuticals, Inc. Cash Incentive Bonus Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 17, 2015.)
10.8*	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2009, filed August 4, 2009.)
10.9*	Trap-2 Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2009, filed August 4, 2009.)
10.10*	Amended and Restated Collaboration Agreement, dated as of February 23, 2015, by and between Sanofi-Aventis US LLC and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2015, filed May 7, 2015.)

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10.11*	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2006, filed November 6, 2006.)
10.11.1*	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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)
10.12	License and Collaboration Agreement, dated as of January 10, 2014, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2014, filed May 8, 2014.)
10.13	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and the Registrant. (Incorporated by reference from the Form 8-K for the Registrant, filed December 22, 2006.)
10.13.1*	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 14, 2007. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2007, filed November 7, 2007.)
10.13.2	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 30, 2008. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2008, filed November 5, 2008.)
10.13.3	Third Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.)
10.13.4	Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of December 3, 2009. (Incorporated by reference from the Form 8-K for the Registrant, filed December 8, 2009.)
10.13.5	Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010. (Incorporated by reference from the Form 8-K for the Registrant, filed February 16, 2010.)
10.13.6	Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2010, filed July 28, 2010.)
10.13.7	Seventh Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of December 22, 2010. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2010, filed February 17, 2011.)
10.13.8	Eighth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 1, 2011. (Incorporated by reference from the Form 10-Q for the Registrant for the quarter ended September 30, 2011, filed October 27, 2011.)
10.13.9	Ninth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of September 30, 2011. (Incorporated by reference from the Form 10-Q for the Registrant for the quarter ended September 30, 2011, filed October 27, 2011.)
10.13.10	Tenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of October 25, 2012. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2015, filed August 4, 2015.)
10.13.11	Eleventh Amendment to Lease by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 3, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.13.12	Twelfth Amendment to Lease by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of May 31, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.13.13	

	Thirteenth Amendment to Lease by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of May 31, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.13.14	Fourteenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of October 25, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2015, filed August 4, 2015.)
10.13.15	Fifteenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 12, 2014. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2015, filed August 4, 2015.)
10.13.16	Sixteenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 30, 2015. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2015, filed August 4, 2015.)

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10.13.17	Seventeenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 10, 2015. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.14	Mt. Pleasant Lease by and between BMR-Landmark at Eastview LLC and the Registrant, dated April 3, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.14.1	First Amendment to Mt. Pleasant Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 30, 2015. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2015, filed August 4, 2015.)
10.15*	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2007, filed May 4, 2007.)
10.15.1*	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. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2010, filed October 28, 2010.)
10.16*	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant. (Incorporated by reference from the Form 10-K/A for the Registrant, for the year ended December 31, 2009, filed June 2, 2010.)
10.16.1*	Amendment No. 1 to Amended and Restated Discovery and Preclinical Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.17*	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. (Incorporated by reference from the Form 10-K/A for the Registrant, for the year ended December 31, 2009, filed June 2, 2010.)
10.17.1*	First Amendment to Amended and Restated License and Collaboration Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 1, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.17.2*	Amendment No. 2 to Amended and Restated License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.18	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. (Incorporated by reference from the Form 8-K for the Registrant, filed January 13, 2014.)
10.19*	Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2008, filed August 1, 2008.)
10.20	Purchase Agreement, dated as of October 18, 2011, between the Registrant and Goldman, Sachs & Co. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.21	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.22	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)

10.22.1	Amendment, dated as of May 15, 2014, to the Master Terms and Conditions for Warrants, between Goldman, Sachs & Co. and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2014, filed August 5, 2014.)
10.22.2	Second Amendment, dated as of November 25, 2014, to the Master Terms and Conditions for Warrants, between Goldman, Sachs & Co. and the Registrant. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)

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10.22.3	Third Amendment, dated as of February 27, 2015, to the Master Terms and Conditions for Warrants, between Goldman, Sachs & Co. and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2015, filed May 7, 2015.)
10.23	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.24	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.24.1	Amendment, dated as of May 13, 2014, to the Master Terms and Conditions for Warrants, between Citibank, N.A. and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2014, filed August 5, 2014.)
10.25	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.26	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.26.1	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. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2014, filed August 5, 2014.)
10.26.2	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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)
10.26.3	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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)
10.26.4	Fourth Amendment, dated as of November 15, 2015, to the Master Terms and Conditions for Warrants, between Credit Suisse Capital LLC (as assignee of Credit Suisse International) and the Registrant.
10.27	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.28	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. (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
10.28.1	Amendment, dated as of May 16, 2014, to the Master Terms and Conditions for Warrants, between Morgan Stanley & Co. International plc and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2014, filed August 5, 2014.)
10.28.2	Second Amendment, dated as of August 5, 2015, to the Master Terms and Conditions for Warrants, between Morgan Stanley & Co. International plc and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.29*	

	Non-exclusive License and Partial Settlement Agreement with Genentech, Inc. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2011, filed February 21, 2012.)
10.29.1*	Amended and Restated Non-Exclusive License and Settlement Agreement by and between Genentech, Inc. and the Registrant, effective May 17, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.29.2*	Non-Exclusive License and Settlement Agreement by and between Genentech, Inc., the Registrant, Sanofi U.S. Services, Inc., and Sanofi-Aventis U.S. LLC, effective May 17, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)

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10.29.3	Agreement dated May 17, 2013 between Bayer Pharma AG, Bayer Australia Limited, the Registrant, Regeneron UK Ltd and Genentech Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.30*	Letter Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 2, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.31	Credit Agreement, dated as of March 19, 2015, by and among the Registrant, as a borrower and guarantor; certain direct and indirect subsidiaries of the Registrant, as the initial subsidiary borrowers; JPMorgan Chase Bank, N.A., as administrative agent; Bank of America, N.A. and U.S. Bank National Association, as co-syndication agents; Barclays Bank PLC, Citibank, N.A., Credit Suisse AG, Cayman Islands Branch, Fifth Third Bank and Morgan Stanley MUFG Loan Partners, LLC, as co-documentation agents; JPMorgan Chase Bank, N.A., Bank of America, N.A. and U.S. Bank National Association, as the issuing banks; JPMorgan Chase Bank, N.A., as the swingline lender; and the other lenders party thereto from time to time. (Incorporated by reference from the Form 8-K for the Registrant, filed March 23, 2015.)
10.32*	Immuno-oncology Discovery and Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.33*	Immuno-oncology License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.34*	Collaboration Agreement, dated as of September 29, 2015, by and between Regeneron Ireland and Mitsubishi Tanabe Pharma Corporation. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
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.
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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*	Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.
+	Indicates a management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

Date: February 11, 2016

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

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer, and each of them, his or her true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ LEONARD S. SCHLEIFER Leonard S. Schleifer, M.D., Ph.D.	President, Chief Executive Officer, and Director (Principal Executive Officer)	February 11, 2016
/s/ ROBERT E. LANDRY Robert E. Landry	Senior Vice President, Finance and Chief Financial Officer (Principal Financial Officer)	February 11, 2016
/s/ DOUGLAS S. McCORKLE Douglas S. McCorkle	Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)	February 11, 2016
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	Chief Scientific Officer, President, Regeneron Laboratories, and Director	February 11, 2016
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	Chairman of the Board	February 11, 2016
/s/ CHARLES A. BAKER Charles A. Baker	Director	February 11, 2016
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	Director	February 11, 2016
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	Director	February 11, 2016
/s/ CHRISTINE A. POON Christine A. Poon	Director	February 11, 2016
/s/ ARTHUR F. RYAN Arthur F. Ryan	Director	February 11, 2016
/s/ GEORGE L. SING George L. Sing	Director	February 11, 2016
/s/ MARC TESSIER-LAVIGNE Marc Tessier-Lavigne, Ph.D.	Director	February 11, 2016

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REGENERON PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive income, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, effective December 31, 2015, the Company retrospectively changed the presentation of deferred income tax assets and liabilities.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 11, 2016

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

	December 31, 2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$809,102	$648,719
Marketable securities	236,121	251,761
Accounts receivable - trade, net	1,152,489	739,379
Accounts receivable from Sanofi	153,152	111,510
Accounts receivable from Bayer HealthCare	162,152	125,483
Inventories	238,578	128,861
Prepaid expenses and other current assets	163,501	79,046
Total current assets	2,915,095	2,084,759
Marketable securities	632,162	460,154
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	1,594,120	974,309
Deferred tax assets	461,945	315,416
Other assets	5,810	3,034
Total assets	$5,609,132	$3,837,672
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$644,112	$483,489
Deferred revenue from Sanofi, current portion	101,573	15,927
Deferred revenue - other, current portion	51,914	58,098
Other current liabilities	13,563	97,146
Total current liabilities	811,162	654,660
Deferred revenue from Sanofi	582,664	62,819
Deferred revenue - other	82,015	72,430
Facility lease obligations	362,919	310,938
Convertible senior notes	—	146,773
Other long-term liabilities	115,535	39,801
Total liabilities	1,954,295	1,287,421
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,913,776 in 2015 and 1,973,368 in 2014	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 106,378,001 in 2015 and 102,475,154 in 2014	106	102
Additional paid-in capital	3,099,526	2,450,782
Retained earnings	852,700	216,644

Accumulated other comprehensive income	8,572	52,251
Treasury stock, at cost; 3,642,820 shares in 2015 and 2,017,732 in 2014	(306,069)	(169,530)
Total stockholders' equity	3,654,837	2,550,251
Total liabilities and stockholders' equity	$5,609,132	$3,837,672

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

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

	Year Ended December 31,		
	2015	2014	2013
Statements of Operations			
Revenues:			
Net product sales	$2,689,478	$1,750,762	$1,425,839
Sanofi collaboration revenue	758,873	541,299	430,111
Bayer HealthCare collaboration revenue	580,488	495,555	220,289
Other revenue	74,889	31,941	28,506
	4,103,728	2,819,557	2,104,745
Expenses:			
Research and development	1,620,577	1,271,353	859,947
Selling, general, and administrative	838,526	519,267	346,393
Cost of goods sold	241,702	129,030	118,048
Cost of collaboration and contract manufacturing	151,007	75,988	37,307
	2,851,812	1,995,638	1,361,695
Income from operations	1,251,916	823,919	743,050
Other income (expense):			
Investment and other income (expense)	6,283	8,157	(231)
Interest expense	(14,241)	(37,372)	(46,437)
Loss on extinguishment of debt	(18,861)	(33,469)	—
	(26,819)	(62,684)	(46,668)
Income before income taxes	1,225,097	761,235	696,382
Income tax expense	(589,041)	(423,109)	(282,644)
Net income	$636,056	$338,126	$413,738
Net income per share - basic	$6.17	$3.36	$4.23
Net income per share - diluted	$5.52	$2.98	$3.72
Weighted average shares outstanding - basic	103,061	100,612	97,917
Weighted average shares outstanding - diluted	115,230	113,413	111,290
Statements of Comprehensive Income			
Net income	$636,056	$338,126	$413,738
Other comprehensive income (loss):			
Unrealized (loss) gain on marketable securities, net of tax	(43,679)	53,439	(22)
Comprehensive income	$592,377	$391,565	$413,716

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

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REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2015, 2014, and 2013
(In thousands)

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			Shares	Amount		
Balance, December 31, 2012	2,069	$ 2	95,223	$ 95	$ 1,792,907	$ (535,220)	—	—	$ (1,166)	$ 1,256,618
Issuance of Common Stock in connection with exercise of stock options	—	—	3,052	3	54,759	—	—	—	—	54,762
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(701)	(1)	(195,086)	—	—	—	—	(195,087)
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	38	—	5,718	—	—	—	—	5,718
Issuance of restricted Common Stock under Long-Term Incentive Plan	—	—	6	—	—	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(49)	—	49	—	—	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	217,080	—	—	—	—	217,080
Excess tax benefit from stock-based compensation	—	—	—	—	211,909	—	—	—	—	211,909
Net income	—	—	—	—	—	413,738	—	—	—	413,738
Other comprehensive loss	—	—	—	—	—	—	—	—	(22)	(22)
Balance, December 31, 2013	2,020	2	97,667	97	2,087,287	(121,482)	—	—	(1,188)	1,964,716

Issuance of Common Stock in connection with exercise of stock options	—	—	3,468	4	125,893	—	—	—	—	125,897
Common Stock tendered upon exercise of stock options in connection with employee tax obligations	—	—	(754)	(1)	(267,583)	—	—	—	—	(267,584)
Issuance of Common Stock in connection with conversion of convertible senior notes	—	—	2,018	2	691,354	—	—	—	—	691,356
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	21	—	13,125	—	—	—	—	13,125
Issuance of restricted Common Stock under Long-Term Incentive Plan	—	—	8	—	—	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(47)	—	47	—	—	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	326,815	—	—	—	—	326,815

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CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Class A Common Stock		Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			Shares	Amount		
Excess tax benefit from stock-based compensation	—	—	—	—	439,278	—	—	—	—	439,278
Acquisition of Common Stock in connection with exercise of convertible note hedges	—	—	—	—	169,530	—	(2,018)	$(169,530)	—	—
Reduction of warrants	—	—	—	—	(294,552)	—	—	—	—	(294,552)
Reclassification of warrant liability	—	—	—	—	(148,496)	—	—	—	—	(148,496)
Reduction of equity component of convertible senior notes	—	—	—	—	(691,869)	—	—	—	—	(691,869)
Net income	—	—	—	—	—	338,126	—	—	—	338,126
Other comprehensive income, net of tax	—	—	—	—	—	—	—	—	53,439	53,439
Balance, December 31, 2014	1,973	2	102,475	102	2,450,782	216,644	(2,018)	(169,530)	52,251	2,550,251
Issuance of Common Stock in connection with exercise of stock options	—	—	2,457	2	215,460	—	—	—	—	215,462
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(298)	—	(160,538)	—	—	—	—	(160,538)
Issuance of Common Stock in connection with conversion of convertible senior notes	—	—	1,625	2	818,358	—	—	—	—	818,360
Issuance of Common Stock in connection	—	—	31	—	15,382	—	—	—	—	15,382

with Company 401(k) Savings Plan contribution										
Issuance of restricted Common Stock under Long-Term Incentive Plan	—	—	28	—	—	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(60)	—	60	—	—	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	464,022	—	—	—	—	464,022
Excess tax benefit from stock-based compensation	—	—	—	—	405,317	—	—	—	—	405,317
Acquisition of Common Stock in connection with exercise of convertible note hedges	—	—	—	—	136,539	—	(1,625)	(136,539)	—	—
Reduction of warrants	—	—	—	—	(449,456)	—	—	—	—	(449,456)
Reclassification of warrant liability	—	—	—	—	23,317	—	—	—	—	23,317
Reduction of equity component of convertible senior notes	—	—	—	—	(819,657)	—	—	—	—	(819,657)

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CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Class A Common Stock		Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Treasury Stock		Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			Shares	Amount		
Net income	—	—	—	—	—	636,056	—	—	—	636,056
Other comprehensive loss, net of tax	—	—	—	—	—	—	—	—	(43,679)	(43,679)
Balance, December 31, 2015	1,913	$2	106,378	$106	$3,099,526	$852,700	(3,643)	$(306,069)	$8,572	$3,654,837

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

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

	Year Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net income	$636,056	$338,126	$413,738
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	74,909	52,686	41,204
Non-cash compensation expense	459,049	321,750	215,377
Loss on extinguishment of debt	18,861	33,469	—
Other non-cash charges and expenses, net	33,701	44,102	46,751
Deferred taxes	(121,623)	(53,276)	62,195
Changes in assets and liabilities:			
Increase in Sanofi, Bayer HealthCare, and trade accounts receivable	(491,421)	(34,927)	(245,472)
Increase in inventories	(111,825)	(56,947)	(47,956)
(Increase) decrease in prepaid expenses and other assets	(79,476)	(45,327)	7,571
Increase (decrease) in deferred revenue	608,892	(8,403)	(41,496)
Increase in accounts payable, accrued expenses, and other liabilities	303,657	161,182	136,684
Total adjustments	694,724	414,309	174,858
Net cash provided by operating activities	1,330,780	752,435	588,596
Cash flows from investing activities:			
Purchases of marketable securities	(557,105)	(564,188)	(577,278)
Sales or maturities of marketable securities	327,437	476,417	378,146
Capital expenditures	(677,933)	(333,006)	(156,323)
Net cash used in investing activities	(907,601)	(420,777)	(355,455)
Cash flows from financing activities:			
Proceeds (payments) in connection with facility and capital lease obligations	26,020	(1,095)	(2,024)
Repayments of convertible senior notes	(166,467)	(220,639)	—
Payments in connection with reduction of outstanding warrants	(573,487)	(294,552)	—
Proceeds from issuance of Common Stock	206,358	126,045	57,393
Payments in connection with Common Stock tendered for employee tax obligations	(160,537)	(267,584)	(195,087)
Excess tax benefit from stock-based compensation	405,317	439,278	211,909
Net cash (used in) provided by financing activities	(262,796)	(218,547)	72,191
Net increase in cash and cash equivalents	160,383	113,111	305,332
Cash and cash equivalents at beginning of period	648,719	535,608	230,276
Cash and cash equivalents at end of period	$809,102	$648,719	$535,608
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	$10,582	$20,348	$23,197
Cash paid for income taxes	$276,092	$59,847	$1,057

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

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REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the Years Ended December 31, 2015, 2014, and 2013
(Unless otherwise noted, dollars in thousands, except per share data)

1. Business Overview and Summary of Significant Accounting Policies

Organization and Business

Regeneron Pharmaceuticals, Inc. and its subsidiaries (collectively, the "Company" or "Regeneron") is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. The Company has product candidates in development in areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. The Company is a party to collaboration agreements to develop certain of these product candidates (see Note 3). The Company currently has 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"), diabetic macular edema ("DME"), macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO"). EYLEA is also available in Japan and the EU for the treatment of myopic choroidal neovascularization ("mCNV") and in the United States for the treatment of diabetic retinopathy in patients with DME.
- Praluent® (alirocumab) Injection, which was approved by the U.S. Food and Drug Administration ("FDA") in July 2015 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease ("ASCVD"), who require additional lowering of low-density lipoprotein ("LDL") cholesterol. In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (heterozygous familial hypercholesterolemia ("HeFH") and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.
- ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"), including Familial Cold Auto-inflammatory Syndrome ("FCAS") and Muckle-Wells Syndrome ("MWS"), in adults and children 12 and older.

The Company operates in one business segment, which includes all activities related to the discovery, development, and commercialization of pharmaceutical products for the treatment of serious medical conditions. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, product development, obtaining regulatory approvals, market acceptance, competition, and obtaining and enforcing patents.

Basis of Presentation

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

The previously issued (i) Consolidated Balance Sheet as of December 31, 2014 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and (ii) Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2014 and 2013, Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013, and Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, have each been revised in this Annual Report on Form 10-K to reflect a correction in the Company's accounting for certain stock option awards. See Note 14.

In addition, the previously issued Consolidated Balance Sheet as of December 31, 2014 in this Annual Report on Form 10-K was revised to reflect a correction related to the accounting for costs incurred in connection with commercial bulk drug product manufactured by the Company, but not billed, under the Company's collaboration agreements with Sanofi and Bayer HealthCare LLC, and the related tax impacts. The correcting adjustments resulted in a reduction to both accounts receivable and deferred revenue by $41.0 million, and reduced both income tax assets, net and additional paid-in capital by $14.2 million. The previously issued Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013 were also revised in this Annual Report on Form 10-K to reflect a $9.3 million and $4.9 million increase, respectively, in cash flows from operating activities and

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a corresponding reduction in cash flows from financing activities related to the tax impact of these adjustments. These adjustments had no impact on the Company's previously issued Consolidated Statements of Operations and Comprehensive Income in any reporting period. The Company determined that the error is not material to any previously-issued financial statements.

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

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include provisions related to product sales, such as rebates, chargebacks, and distribution-related fees; periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements; periods over which certain clinical trial costs are recognized; fair value of stock options; inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value; capitalization of inventory costs associated with the Company's products prior to regulatory approval; deferred tax asset valuation allowances; and the assessment of uncertain tax positions.

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

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

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

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the Balance Sheet for cash and cash equivalents approximates its fair value.

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company invests its excess cash primarily in marketable securities issued by investment grade institutions. The Company considers its marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets are carried at fair value and the unrealized gains and losses are included in accumulated other comprehensive income (loss). If a decline in the value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss as a charge against income. The Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

Accounts Receivable - Trade

The Company's trade accounts receivable arise from product sales and represent amounts due from its distributors and specialty pharmacies (collectively, the Company's "customers"), which are all located in the United States. The

Company monitors the financial performance and credit worthiness of its large customers so that it can properly assess and respond to changes in their credit profile. The Company provides reserves against trade receivables for estimated losses, if any, that may result from a customer's inability to pay. Amounts determined to be uncollectible are written-off against the reserve.

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

Inventories

Inventories are stated at the lower of cost or estimated realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method.

The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The 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.

The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of goods sold to write down such unmarketable inventory to its estimated realizable value.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term. Costs of construction of certain long-lived assets include capitalized interest, which is amortized over the estimated useful life of the related asset. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	10-30 years
Laboratory and other equipment	3-10 years
Furniture and fixtures	5 years

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Revenue Recognition

a. Product Revenue

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

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

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. Calculating these provisions involves estimates

and judgments. The Company reviews its estimates of rebates, chargebacks, and other applicable provisions each period and records any necessary adjustments in the current period's net product sales.

Government Rebates and Chargebacks: The Company estimates reductions to product sales for Medicaid and Veterans' Administration ("VA") programs, and for certain other qualifying federal and state government programs. Based upon the

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

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

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

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

b. Collaboration Revenue

The Company earns collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize the Company's technology platforms. These arrangements may require the Company 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 the Company in the form of non-refundable up-front payments, milestone payments, payments for development and commercialization activities, and sharing of profits or losses arising from the commercialization of products.

In connection with non-refundable up-front payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain regulatory approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays, or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications.

In arrangements involving multiple deliverables, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverables in the arrangement meet certain criteria, including whether the delivered item or items has value to the collaborator on a standalone basis. The arrangement's consideration that is fixed and determinable is allocated to each separate unit of accounting based on the relative selling price of each deliverable. If multiple collaboration activities or rights do not require separation, they are combined into a single unit of accounting and recognized over the performance period, which is the period over which the Company is obligated to deliver goods or services. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances.

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Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the enhancement in value to the related development product candidate, (ii) the Company's performance and 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.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as collaboration revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, the Company also recognizes, as additional research and development expense in the period when its collaborator incurs development expenses, the portion of the collaborator's development expenses that the Company is obligated to reimburse. The Company may also be obligated to use commercially reasonable efforts to supply commercial bulk product to its collaborators. In such cases, the Company is reimbursed for its manufacturing costs as commercial product is shipped to its collaborators; however, recognition of such cost reimbursements as collaboration revenue is deferred until the product is sold by the Company's collaborators to third-party customers, at which time the Company's risk of inventory loss no longer exists. In addition, at that time, the related manufacturing costs for the sold product, which had been capitalized into inventory, are recognized by the Company.

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

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. Costs associated with research and development are expensed.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations ("CROs"), independent clinical investigators, and other

third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and/or the period over which clinical investigators or CROs are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

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For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues expenses on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's Long-Term Incentive Plans to employees and non-employee members of the Company's board of directors based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Common Stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Uncertain tax positions, 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 recognition and measurement criteria. The Company re-evaluates uncertain tax positions and consider various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, and changes in facts or circumstances related to a tax position. The Company adjusts the level of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain positions. The Company recognizes interest and penalties related to income tax matters in income tax expense.

Per Share Data

Basic net income per share is computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Basic net income per share excludes restricted stock awards until vested. Diluted net income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when

dilutive, (ii) Common Stock to be issued upon the assumed conversion of the Company's convertible senior notes, which are included under the "if-converted method" when dilutive, and (iii) Common Stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive.

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Concentration of Credit Risk

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

Concentrations of credit risk with respect to accounts receivable are significant. Accounts receivable from product sales of EYLEA and ARCALYST are due from several distributors and specialty pharmacies, who are the Company's customers. As of December 31, 2015 and 2014, one individual customer accounted for 68% and 70%, respectively, of the Company's net trade accounts receivable balances. The Company has contractual payment terms with each of its customers, and the Company monitors its customers' financial performance and credit worthiness so that it can properly assess and respond to any changes in their credit profile. In addition, the Company may insure a portion of its accounts receivables within its overall risk management practices. As of December 31, 2015 and 2014, there were no reserves against trade accounts receivable. In addition, during the years ended December 31, 2015, 2014, and 2013, the Company did not recognize any charges for write-offs of trade accounts receivable.

Recently Issued Accounting Standards

In November 2015, the FASB issued Accounting Standards Update 2015-17, Balance Sheet Classification of Deferred Taxes, which is intended to simplify the balance sheet presentation of deferred income taxes. Current accounting principles require an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in its balance sheet. The amendments require that deferred tax liabilities and assets be classified as noncurrent in its balance sheet. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Companies may apply the new provisions either retrospectively or on a prospective basis, and early adoption is permitted. The Company early adopted the amendments effective December 31, 2015 on a retrospective basis. The impact of the adoption of the amendments on the Company's Consolidated Balance Sheet as of December 31, 2014 was a $46.2 million reclassification of current deferred tax assets to noncurrent deferred tax assets.

In May 2014, the FASB issued Accounting Standards Update 2014-09, 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. In July 2015, the FASB decided to delay the effective date of the new standard by one year; as a result, the new standard will be effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption will be permitted, but no earlier than 2017 for calendar year-end entities. 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. The Company has not yet determined its method of transition and is evaluating the impact that this guidance will have on the Company's financial statements.

In January 2016, the FASB issued Accounting Standards Update 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments require equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and separate presentation of financial assets and financial liabilities by measurement category and form of financial asset. Additionally, the amendments eliminate the requirement to disclose the methods and significant assumptions used to estimate the fair value of financial instruments. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Other than an amendment relating to presenting in comprehensive income the portion of the total change in the

fair value of a liability resulting from a change in instrument-specific credit risk (if the entity has elected to measure the liability at fair value), early adoption is not permitted. The Company is evaluating the impact that this guidance will have on the Company's financial statements.

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2. Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. The Company received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in July 2014, macular edema following BRVO in October 2014, and diabetic retinopathy in patients with DME in March 2015. EYLEA net product sales in the United States totaled $2,676.0 million, $1,736.4 million, and $1,408.7 million for the years ended December 31, 2015, 2014, and 2013, respectively.

ARCALYST net product sales totaled $13.5 million, $14.4 million, and $17.1 million for the years ended December 31, 2015, 2014, and 2013, respectively.

For the years ended December 31, 2015, 2014, and 2013, the Company recorded 67%, 73%, and 76%, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions for the years ended December 31, 2015, 2014, and 2013.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2012	$2,983	$15,298	$545	$18,826
Provision related to current period sales	25,936	62,984	955	89,875
Credits/payments	(24,519)	(58,619)	(962)	(84,100)
Balance as of December 31, 2013	4,400	19,663	538	24,601
Provision related to current period sales	33,117	77,160	1,578	111,855
Credits/payments	(34,434)	(75,657)	(1,584)	(111,675)
Balance as of December 31, 2014	3,083	21,166	532	24,781
Provision related to current period sales	61,124	122,466	9,600	193,190
Credits/payments	(57,788)	(95,319)	(9,615)	(162,722)
Balance as of December 31, 2015	$6,419	$48,313	$517	$55,249

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. Orphan drugs sales, including ARCALYST, are not subject to the fee. In July 2014, the Internal Revenue Service ("IRS") issued final regulations that provide guidance on the Branded Prescription Drug Fee. As a result of the issuance of these final IRS regulations, 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. The impact of the incremental charge in the third quarter of 2014 was $40.6 million, which was included in selling, general, and administrative expenses.

3. Collaboration Agreements

The Company has entered into various agreements related to its activities to research, develop, manufacture, and commercialize product candidates and utilize its technology platforms. Significant agreements of this kind are described below.

a. Sanofi

Sanofi owned a total of 23,108,570 shares of the Company's Common Stock as of December 31, 2015, a portion of which was purchased in connection with the companies' ZALTRAP® and antibody collaborations described below. See Note 13 for a description of the investor agreement between Sanofi and the Company.

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The collaboration revenue the Company earned from Sanofi is detailed below:

	Year Ended December 31,		
Sanofi Collaboration Revenue	2015	2014	2013
Antibody:			
Reimbursement of Regeneron research and development expenses	$735,439	$547,761	$453,489
Reimbursement of Regeneron commercialization-related expenses	157,350	19,480	1,868
Regeneron's share of losses in connection with commercialization of antibodies	(240,042)	(41,378)	—
Up-front payments to Sanofi for acquisition of rights related to two antibodies	—	—	(20,000)
Other	10,243	10,243	10,243
Total Antibody	662,990	536,106	445,600
Immuno-oncology:			
Reimbursement of Regeneron research and development expenses	39,961	—	—
Other	40,000	—	—
Total Immuno-oncology	79,961	—	—
ZALTRAP:			
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	(4,715)	(30,810)
Reimbursement of Regeneron research and development expenses	686	4,806	5,639
Other	15,236	5,102	9,682
Total ZALTRAP	15,922	5,193	(15,489)
	$758,873	$541,299	$430,111

Other selected financial information in connection with the Company's collaboration agreements with Sanofi is as follows:

	December 31,	
	2015	2014
Antibody:		
Accounts receivable, net	$126,687	$110,559
Deferred revenue	84,237	64,408
Immuno-oncology:		
Accounts receivable, net	$21,394	—
Deferred revenue	600,000	—

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Antibodies

In November 2007, the Company entered into a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). The Antibody Collaboration is governed by the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended). In connection with the execution of the Antibody Discovery Agreement in 2007, the Company received a non-refundable up-front payment of $85.0 million from Sanofi. In addition, under the Antibody Discovery Agreement, Sanofi is funding the Company's research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. In November 2009, the Company and Sanofi amended these collaboration agreements to expand and extend the Antibody Collaboration. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi agreed to fund up to $160.0 million per year of the Company's research activities in 2010 through 2017. However, in July 2015, in connection with the Company’s new immuno-oncology collaboration with Sanofi, as described below, the Company’s Antibody Discovery Agreement and License and Collaboration Agreement with Sanofi were each amended. In connection with these amendments, Sanofi's funding of the Company’s antibody discovery activities under the existing Antibody Collaboration was reduced to up to $145.0 million in 2015, and up to $130.0 million in both 2016 and 2017, or an aggregate reduction of $75.0 million over this three-year period. In addition, the Company's discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will be funded by Sanofi under the terms of the companies’ new immuno-oncology collaboration. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified under the Antibody Discovery Agreement, Sanofi has the option to license rights to the candidate under the License and Collaboration Agreement. If it elects to do so, Sanofi will co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, Sanofi must make a $10 million substantive milestone payment to the Company. If Sanofi does not exercise its option to license rights to a particular drug candidate under the License and Collaboration Agreement, or if Sanofi elects not to continue to co-develop a product candidate, the Company retains the exclusive right to develop and commercialize such drug candidate and Sanofi will receive a royalty on sales, if any. The Company and Sanofi are currently co-developing various therapeutic antibodies under the License and Collaboration Agreement.

Under the License and Collaboration Agreement, agreed-upon worldwide development expenses incurred by both companies during the term of the agreement are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. Consequently, commencing in 2013, the Company recognized as additional research and development expense $92.6 million, $109.7 million, and $17.6 million in 2015, 2014, and 2013, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent and sarilumab. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse Sanofi for 50% of worldwide development expenses that were fully funded by Sanofi and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products. However, the Company is not required to apply more than 10% of its share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs. The Company's contingent reimbursement obligation to Sanofi under the Antibody Collaboration was approximately $1,832 million as of December 31, 2015.

Sanofi will lead commercialization activities for products developed under the License and Collaboration Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from

sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65%(Sanofi)/35% (Regeneron) and ending at 55% (Sanofi)/45% (Regeneron), and losses outside the United States at 55%(Sanofi)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to $250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed $1.0 billion on a rolling twelve-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's Antibody Discovery Agreement, Sanofi funded $30.0 million of agreed-upon costs the Company incurred to expand its manufacturing capacity at its Rensselaer, New York facilities. Additionally, during 2014, Sanofi agreed to fund up to $17.5 million of agreed-upon costs incurred by the Company in connection with expanding the Company's manufacturing capacity at its Rensselaer, New York facility, of which $13.2 million has been received or is receivable

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as of December 31, 2015. Payments received from Sanofi to fund agreed-upon expansions of the Company's manufacturing capacity are initially recorded as deferred revenue by the Company and are being recognized as collaboration revenue over the related performance period.

With respect to each antibody product which enters development under the License and Collaboration Agreement, Sanofi or the Company may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to Sanofi within thirty days of the date that Sanofi enters joint development of such antibody product under the License and Collaboration Agreement. Each of the Antibody Discovery Agreement and the License and Collaboration 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 Antibody Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, Sanofi would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse Sanofi for development costs out of any future profits from collaboration products will terminate. In the event of termination of the amended Antibody Discovery Agreement, the Company retains exclusive rights to continue the development and/or commercialization of such product(s). Upon expiration of the amended Antibody Discovery Agreement, Sanofi has an option to license the Company's VelocImmune® technology for an annual license fee plus royalties on any future sales of products developed using VelocImmune technology.

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with Sanofi, which extended through December 2012, to use Regeneron's proprietary VelociGene® technology platform to supply Sanofi with genetically modified mammalian models of gene function and disease (the "VelociGene Agreement"). The VelociGene Agreement provided for minimum annual order quantities for the term of the agreement, for which the Company received payments totaling $21.5 million. Payments received were initially recorded as deferred revenue by the Company and are being recognized as collaboration revenue over the related performance period.

In May 2013, the Company acquired from Sanofi full exclusive rights to two families of novel antibodies invented at Regeneron and previously included in the Company's Antibody Collaboration with Sanofi. The Company acquired full rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors and ligands in ophthalmology and all other indications and to antibodies targeting the angiopoietin-2 (Ang2) receptor and ligand in ophthalmology. As noted in the "Sanofi collaboration revenue" table above, in 2013, with respect to PDGF antibodies, the Company made a $10.0 million up-front payment to Sanofi, and, with respect to Ang2 antibodies in ophthalmology, the Company made a $10.0 million up-front payment to Sanofi. In addition, with respect to PDGF antibodies, the Company made two $5.0 million development milestone payments to Sanofi in 2014 and a $10.0 million development milestone payment to Sanofi in 2015, each of which was recorded as research and development expense. The Company is obligated to pay up to $20 million in additional potential development milestones as well as royalties on any future sales of PDGF antibodies.

In July 2014, in connection with the Company's Antibody Collaboration with Sanofi, the Company purchased an FDA priority review voucher from a third party for $67.5 million. The Company and Sanofi equally shared the priority review voucher's purchase price, and the Company's share of the cost, or $33.8 million, was recorded as a research and development expense during 2014. The Company subsequently transferred the voucher to Sanofi, which used the priority review voucher in connection with the Biologics License Application submission to the FDA for Praluent.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent and sarilumab. Effective in the second and fourth quarters of 2014, the Company and Sanofi began sharing pre-launch

commercialization expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement. Consequently, the Company began recording its share of losses in connection with preparing to commercialize these two antibody candidates within Sanofi collaboration revenue. As described in Note 1 above, in July 2015, the FDA approved Praluent in the United States and in September 2015, the European Commission granted marketing authorization of Praluent. Therefore, commencing in 2015, the Company also recorded within Sanofi collaboration revenue its share of the Antibody Collaboration's losses in connection with commercialization of Praluent.

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Immuno-Oncology

In July 2015, the Company and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement ("IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to the Company. Pursuant to the IO Discovery Agreement, the Company will spend up to $1,090.0 million ("IO Discovery Budget") to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse the Company for up to $825.0 million ("IO Discovery Funding") of these costs, subject to certain annual limits, which consists of (i) $750.0 million in new funding and (ii) $75.0 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery Agreement, as described above. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi’s option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, the Company will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of Investigational New Drug ("IND") Applications, and clinical development through proof-of-concept. The Company will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from Regeneron's share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. However, the Company is not required to apply more than 10% of its share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, the Company will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to the Company. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with the Company through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between the Company and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and the Company will reimburse half of the total development costs for all such candidates from its share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, Sanofi and the Company will share equally, on an ongoing basis, the development costs for the drug candidates for which the Company is the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products. The Company is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop the Company's antibody product candidate targeting the receptor known as Programmed Cell Death protein 1, or PD-1 ("REGN2810"). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. The Company will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. The Company will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2 billion in any consecutive twelve-month period.

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, Sanofi or the Company may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

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At the inception of the IO Collaboration, the Company's significant deliverables consisted of (i) license to certain rights and intellectual property, (ii) providing research and development services, and (iii) manufacturing clinical supplies. The Company concluded that the license did not have standalone value, primarily due to the fact that such rights were not sold separately by the Company, nor could Sanofi receive any benefit from the license without the fulfillment of other ongoing obligations by the Company, including the clinical supply arrangement. Therefore, the deliverables were considered a single unit of accounting. Consequently, the $640.0 million in aggregate up-front payments was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

ZALTRAP

In September 2003, the Company entered into a collaboration agreement ("ZALTRAP Collaboration Agreement") with Aventis Pharmaceuticals Inc. (predecessor to Sanofi U.S.) to jointly develop and commercialize ZALTRAP. Under the terms of the ZALTRAP Collaboration Agreement, as amended, Regeneron and Sanofi shared co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan, and the Company was entitled to receive a percentage of sales of ZALTRAP in Japan. Sanofi commenced sales of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with 5-fluorouracil, leucovorin, irinotecan ("FOLFIRI"), for patients with metastatic colorectal cancer ("mCRC") that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in 2012 and in certain European and other countries in 2013.

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"), with an effective date of July 1, 2014. Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. The Company will also be paid for all quantities of ZALTRAP manufactured by it, pursuant to a supply agreement, through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities, or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement. Unless terminated earlier in accordance with its provisions, the Amended ZALTRAP Agreement will continue to be in effect until such time as neither Sanofi nor its affiliates or sublicensees is developing or commercializing ZALTRAP.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015, the Company recognized $14.9 million of collaboration revenue, which was previously recorded as deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since the risk of inventory loss no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as the Company had no further performance obligations. In addition, during the year ended December 31, 2015, the Company recorded $38.8 million, in other revenue, primarily related to (i) revenues earned from Sanofi based on a percentage of net sales of ZALTRAP and (ii) revenues earned from Sanofi for manufacturing ZALTRAP commercial supplies.

b. Bayer HealthCare LLC

The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States. The Company and Bayer HealthCare share the costs of the development of EYLEA. Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME in the third quarter of 2014, mCNV (in Japan) in the fourth quarter of 2014, and macular edema following BRVO in the second quarter of 2015. Bayer HealthCare markets EYLEA outside the United States, where, for countries other than Japan, the Company and Bayer

HealthCare will share equally in profits and losses from sales of EYLEA. The Company is entitled to receive a percentage of between 33.5% and 40.0% of EYLEA annual sales in Japan. Within the United States, the Company is responsible for commercialization of EYLEA and retains exclusive rights to all profits from such commercialization in the United States.

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In 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta).

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

	Year Ended December 31,		
Bayer HealthCare Collaboration Revenue	2015	2014	2013
EYLEA:			
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$466,667	$301,302	$101,494
Sales and substantive development milestones	15,000	105,000	70,000
Cost-sharing of Regeneron EYLEA development expenses	8,887	23,383	20,905
Other	69,466	52,390	27,890
Total EYLEA	560,020	482,075	220,289
PDGFR-beta antibody:			
Cost-sharing of REGN2176-3 development expenses	10,075	2,848	—
Other	10,393	10,632	—
Total PDGFR-beta	20,468	13,480	—
	$580,488	$495,555	$220,289

Other selected financial information in connection with the Company's collaboration agreements with Bayer HealthCare is as follows:

	December 31,	
	2015	2014
EYLEA:		
Accounts receivable, net	$160,755	$124,293
Deferred revenue	46,694	28,752
PDGFR-beta antibody:		
Accounts receivable, net	$1,397	$1,191
Deferred revenue	9,522	19,909

EYLEA outside the United States

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of EYLEA. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of $75.0 million. The Company also received from Bayer HealthCare a $20.0 million development milestone payment in 2007 (which, for the purpose of revenue recognition, was not considered substantive). The $75.0 million up-front payment and the $20.0 million milestone payment are being recognized as collaboration revenue over the related estimated performance period in accordance with the Company's revenue recognition policy as described in Note 1.

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

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agreement without cause with at least six months' or twelve months' advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to EYLEA.

The Company is obligated to reimburse Bayer HealthCare out of its share of the collaboration profits (including the Company's percentage of sales of EYLEA in Japan) for 50% of the agreed-upon development expenses that Bayer HealthCare has incurred in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. The Company's contingent reimbursement obligation to Bayer HealthCare was approximately $258 million as of December 31, 2015.

In 2013, the Company earned a $15.0 million and a $10.0 million substantive milestone payment related to marketing and pricing approval, respectively, of EYLEA for the treatment of macular edema secondary to CRVO. In addition, in 2013, the Company earned, and recorded as revenue, $45.0 million of sales milestone payments from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States achieving certain specified levels starting at $200 million over a twelve-month period. In 2014, the Company earned, and recorded as revenue, $90.0 million of sales milestone payments from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States achieving certain specified levels starting at $500 million over a twelve-month period. In addition, in connection with a November 2013 agreement under which Bayer HealthCare obtained rights to use certain of the Company's EYLEA clinical data for a regulatory filing, the Company earned, and recorded as revenue, a $15.0 million sales milestone payment in 2014 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 2015, the Company earned, and recorded as revenue, the final sales milestone payment from Bayer HealthCare, in the amount of $15.0 million, upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period.

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 Regeneron $15.7 million for a defined share of the EYLEA global development costs that the Company had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014 and is included with "Cost-sharing of Regeneron EYLEA development expenses" in the table above. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). The Company is entitled to receive a tiered percentage of EYLEA net sales in Japan.

In periods when Bayer HealthCare incurs agreed-upon EYLEA development expenses that benefit the collaboration and Regeneron, the Company recognizes, as additional research and development expense, the portion of Bayer HealthCare's EYLEA development expenses that the Company is obligated to reimburse. In 2015, 2014, and 2013, the Company recognized as research and development expense $13.7 million, $18.6 million, and $15.3 million, respectively, of EYLEA development expenses that the Company was obligated to reimburse to Bayer HealthCare.

PDGFR-beta antibody outside the United States

In January 2014, the Company 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 aflibercept, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept, is being developed under the agreement. Under the agreement, the Company will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to 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 up-front payment to the Company in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to the Company in 2014 (both of which, for the purpose of revenue recognition, were not considered substantive) and a $5.0 million development milestone payment to the Company in 2015 (which was recognized as a substantive milestone). The Company is eligible to receive a $10.0 million additional future development milestone payment from Bayer HealthCare, although this payment could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

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From inception of the agreement until Bayer HealthCare has the right to opt-in to the collaboration, the Company's sole significant deliverable is research and development services provided in accordance with the agreement. Therefore, the $25.5 million up-front payment was allocated to this deliverable, initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. In addition, the two $2.5 million non-substantive development milestone payments from Bayer HealthCare were also initially recorded as deferred revenue and will be recognized over the same performance period as the up-front payment.

If Bayer HealthCare exercises its right to opt-in to the collaboration, it 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 the Company, pay a $20.0 million development milestone to the Company upon receipt of the first marketing approval in the EU or Japan, share profits and losses from sales outside the United States equally with the Company, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

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

The Company also has the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If the Company opts-out of the collaboration and Bayer HealthCare exercises 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.

Under the agreement, Bayer HealthCare has also agreed to a "standstill" provision, which prohibits Bayer HealthCare and its affiliates from seeking to influence the control of the Company or acquiring more than 20% of the Company's then outstanding shares of Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement or (ii) other specified events.

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

c. Mitsubishi Tanabe Pharma

In September 2015, the Company and Mitsubishi Tanabe Pharma Corporation ("MTPC") entered into a collaboration agreement (the "MTPC Collaboration Agreement") providing MTPC with development and commercial rights to fasinumab, the Company's nerve growth factor antibody in late-stage clinical development, in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the "MTPC Territories"). In connection with the MTPC Collaboration Agreement, MTPC made a $10.0 million non-refundable up-front payment, and in the first quarter of 2016, MTPC became obligated to make an additional $45.0 million payment to the Company. The Company is entitled to receive up to an aggregate of $65.0 million in development milestones if achieved by the Company and $105.0 million in other contingent payments, primarily related to development milestones achieved by MTPC.

Under the MTPC Collaboration Agreement, the Company is obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, the Company will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and is eligible for additional payments up to an aggregate of $100.0

million upon the achievement of specified annual net sales amounts starting at $200 million. Unless terminated earlier in accordance with its provisions, the MTPC Collaboration Agreement will continue to be in effect until such time as MTPC has ceased developing or commercializing fasinumab in the MTPC Territories.

At the inception of the MTPC Collaboration Agreement, the Company's significant deliverables consisted of (i) exclusive rights to develop and commercialize fasinumab in the MTPC Territories, and (ii) manufacturing clinical and commercial supplies. The Company concluded that the license did not have standalone value, as such right was not sold separately by the Company, nor could MTPC receive any benefit from the license without the manufacturing services to be rendered by the Company. Therefore,

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the deliverables were considered a single unit of accounting. Consequently, the $10.0 million up-front payment was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

d. Other

In addition to the collaboration agreements discussed above, the Company has various other collaboration agreements that are not individually, or in the aggregate, significant to its operating results or financial condition at this time. Pursuant to the terms of those agreements, the Company may be required to pay, or it may receive, additional amounts upon the achievement of various development and commercial milestones which in the aggregate could be significant. The Company may also incur, or get reimbursed for, significant research and development costs if the related product candidate(s) were to advance to late stage clinical trials. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay, or it may receive, royalties on future sales. The payment or receipt of these amounts, however, is contingent upon the occurrence of various future events.

4. Technology Licensing Agreement

In March 2007, the Company entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize the Company's VelocImmune technology in its internal research programs to discover human monoclonal antibodies. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a $165.0 million up-front payment to the Company in August 2010, which was deferred upon receipt and is being recognized as revenue ratably over the seven-year period beginning in mid-2011. In addition, Astellas will make a $130.0 million second payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. In connection with the Astellas license agreement, for each of the years ended December 31, 2015, 2014, and 2013, the Company recognized $23.6 million of other revenue. In addition, deferred revenue at December 31, 2015 and 2014 was $57.4 million and $81.0 million, respectively.

5. Marketable Securities

Marketable securities as of December 31, 2015 and 2014 consist of both debt securities of investment grade issuers as well as equity securities. The Company also held restricted marketable securities as of December 31, 2014, consisting of the Company's investment in Avalanche Biotechnologies, Inc. common shares, which were subject to customary transfer restrictions until January 2015 under a lock-up agreement with the underwriters of Avalanche's initial public offering.

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The following tables summarize the Company's investments in marketable securities:

As of December 31, 2015	Amortized Cost Basis	Unrealized Gains	Losses	Fair Value
Unrestricted				
Corporate bonds	$770,092	$156	$(2,565)	$767,683
U.S. government and government agency obligations	51,402	—	(193)	51,209
Municipal bonds	17,930	5	(11)	17,924
Equity securities	17,005	14,461	—	31,466
	$856,429	$14,622	$(2,769)	$868,282
As of December 31, 2014				
Unrestricted				
Corporate bonds	$548,832	$136	$(1,462)	$547,506
U.S. government and government agency obligations	28,596	3	(46)	28,553
Municipal bonds	37,044	37	(43)	37,038
Equity securities	2,005	5,374	—	7,379
	616,477	5,550	(1,551)	620,476
Restricted				
Equity securities	15,000	76,439	—	91,439
	$631,477	$81,989	$(1,551)	$711,915

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of December 31, 2015 mature at various dates through August 2020. The fair values of debt security investments by contractual maturity consist of the following:

	As of December 31,	
	2015	2014
Maturities within one year	$236,121	$251,761
Maturities after one year through five years	600,695	360,208
Maturities after five years through ten years	—	1,128
	$836,816	$613,097

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The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position.

	Less than 12 Months		12 Months or Greater		Total	
As of December 31, 2015	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$668,199	$(2,473)	$23,749	$(92)	$691,948	$(2,565)
U.S. government and government agency obligations	51,215	(193)	—	—	51,215	(193)
Municipal bonds	11,917	(11)	—	—	11,917	(11)
	$731,331	$(2,677)	$23,749	$(92)	$755,080	$(2,769)
As of December 31, 2014						
Corporate bonds	$390,613	$(1,462)	—	—	$390,613	$(1,462)
U.S. government and government agency obligations	25,549	(46)	—	—	25,549	(46)
Municipal bonds	10,779	(43)	—	—	10,779	(43)
	$426,941	$(1,551)	—	—	$426,941	$(1,551)

During the year ended December 31, 2013, the Company recorded an other-than-temporary impairment charge of $2.9 million related to its investment in an equity security. There were no other-than-temporary impairment charges recorded on the Company's investments during 2015 or 2014.

Realized gains and losses are included as a component of investment income. For the year ended December 31, 2015, total realized gains and losses were not material. For the year ended December 31, 2014, total realized gains on sales of marketable securities were $1.2 million, and there were no realized losses. For the year ended December 31, 2013, total realized gains on sales of marketable securities were $1.0 million, and there were no realized losses.

Changes in the Company's accumulated other comprehensive income (loss) for the years ended December 31, 2015, 2014, and 2013 related to unrealized gains and losses on available-for-sale marketable securities. For the years ended December 31, 2015, 2014, and 2013, amounts reclassified from accumulated other comprehensive income (loss) into investment income in the Company's Statements of Operations were related to the 2013 impairment charge on the equity security, and realized gains and losses on sales of marketable securities described above.

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6. Fair Value Measurements

The Company's assets that are measured at fair value on a recurring basis consist of the following:

As of December 31, 2015	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$767,683	—	$767,683
U.S. government and government agency obligations	51,209	—	51,209
Municipal bonds	17,924	—	17,924
Equity securities	31,466	$31,466	—
	$868,282	$31,466	$836,816
As of December 31, 2014			
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$547,506	—	$547,506
U.S. government and government agency obligations	28,553	—	28,553
Municipal bonds	37,038	—	37,038
Equity securities	7,379	$7,379	—
	620,476	7,379	613,097
Restricted			
Equity securities	91,439	—	91,439
	$711,915	$7,379	$704,536

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities in 2015, 2014, and 2013.

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the years ended December 31, 2015 and 2014. During 2015, transfers of marketable securities from Level 2 to Level 1 were $91.4 million in connection with the lapse of the transfer restrictions on the Company's investment in Avalanche common shares in January 2015. The Company's policy for recognition of transfers between levels of the fair value hierarchy is to recognize any transfer at the beginning of the fiscal quarter in which the determination to transfer was made. There were no other transfers of marketable securities between Levels 1, 2, or 3 classifications during the year ended December 31, 2015, and there were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the year ended December 31, 2014.

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As of December 31, 2015 and 2014, the Company had $11.2 million and $169.4 million, respectively, in aggregate principal amount of 1.875% convertible senior notes outstanding. See Note 11. The fair value of the outstanding convertible senior notes was estimated to be $72.8 million and $819.8 million as of December 31, 2015 and 2014, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

7. Inventories

Inventories consist of the following:

	As of December 31,	
	2015	2014
Raw materials	$59,151	$10,923
Work-in-process	132,068	73,519
Finished goods	11,197	10,768
Deferred costs	36,162	33,651
	$238,578	$128,861

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred (see Note 1). In 2015, 2014, and 2013, cost of goods sold included inventory write-downs and reserves totaling $10.6 million, $6.0 million, and $9.1 million, respectively.

8. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	As of December 31,	
	2015	2014
Land	$77,826	$2,768
Building and improvements	760,517	398,981
Leasehold improvements	95,226	42,600
Construction-in-progress	579,834	472,231
Laboratory and other equipment	330,432	253,058
Furniture, computer and office equipment, and other	81,381	58,655
	1,925,216	1,228,293
Less, accumulated depreciation and amortization	(331,096)	(253,984)
	$1,594,120	$974,309

As of December 31, 2015 and 2014, $1,118.4 million and $754.7 million, respectively, of the Company's property, plant, and equipment was located in the United States and $475.7 million and $219.6 million, respectively, was located in Ireland. In 2015, the Company acquired an approximate 100-acre parcel of undeveloped land adjacent to the Company's current Tarrytown, New York location for an aggregate purchase price of $73.0 million.

Depreciation and amortization expense on property, plant, and equipment amounted to $74.9 million, $52.7 million, and $41.2 million for the years ended December 31, 2015, 2014, and 2013, respectively.

Property, plant, and equipment, at cost, as of December 31, 2015 and 2014 included $254.6 million and $236.7 million, respectively, of costs incurred by the Company's landlord to construct laboratory and office facilities in Tarrytown, New York. See Note 12a.

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9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	As of December 31,	
	2015	2014
Accounts payable	$140,962	$99,508
Accrued payroll and related costs	133,223	92,778
Accrued clinical trial expense	88,297	41,555
Accrued sales-related charges, deductions, and royalties	195,986	133,085
Other accrued expenses and liabilities	85,644	116,563
	$644,112	$483,489

10. Deferred Revenue

Deferred revenue consists of the following:

	As of December 31,	
	2015	2014
Current portion:		
Received or receivable from Sanofi (see Note 3a)	$101,573	$15,927
Received or receivable from Bayer HealthCare (see Note 3b)	24,290	33,652
Received for technology license agreement (see Note 4)	23,572	23,572
Other	4,052	874
	$153,487	$74,025
Long-term portion:		
Received or receivable from Sanofi (see Note 3a)	$582,664	$62,819
Received or receivable from Bayer HealthCare (see Note 3b)	31,926	15,007
Received for technology license agreement (see Note 4)	33,851	57,423
Other	16,238	—
	$664,679	$135,249

11. Debt

a. Convertible Debt

In October 2011, the Company issued $400.0 million aggregate principal amount of 1.875% convertible senior notes (the "Notes") in a private placement.

The Notes pay interest semi-annually on April 1 and October 1, and will mature on October 1, 2016 unless earlier converted (which can occur subject to certain conditions) or repurchased. The Notes are convertible, subject to certain conditions, into cash, shares of the Company's Common Stock, or a combination of cash and shares of Common Stock, at the Company's option. The Notes initial conversion price is approximately $84.02 per share. In the event that a fundamental change, as defined in the indenture under which the Notes have been issued, occurs prior to maturity of the Notes, the initial conversion rate may be increased to include additional shares upon conversion, or holders can require the Company to purchase from them all or a portion of their Notes for 100% of the principal value plus any accrued and unpaid interest.

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

As of December 31, 2015, the "if converted value" exceeded the principal amount of the Notes by $70.4 million.

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

In connection with the offering of the Notes in October 2011, the Company entered into convertible note hedge ("call option") and warrant transactions with multiple counterparties, including an affiliate of the initial purchaser of the Notes. The convertible note hedge covers, subject to customary anti-dilution adjustments, the number of shares of the Company's Common Stock that initially underlie the Notes, and are intended to reduce the potential dilutive impact of the conversion feature of the Notes. The convertible note hedge will terminate upon the earlier of the maturity date of the Notes or the first day the Notes are no longer outstanding. The Company paid $117.5 million for the convertible note hedge, which was recorded as a reduction to additional paid-in capital. The warrants have an initial strike price of approximately $103.41 per share, and may be settled in cash or shares of the Company's Common Stock, at the Company's option. The warrants have a dilutive effect to the extent that the market price per share of the Company's Common Stock exceeds the applicable strike price of the warrants. Proceeds received from the warrant transactions totaled $93.8 million and were recorded as additional paid-in capital. The warrants will become exercisable (and, if not exercised, will expire) at various dates during 2017. The original convertible note hedge and warrants were both considered indexed to the Company's Common Stock and classified as equity; therefore, the convertible note hedge and warrants were not accounted for as derivative instruments. The Company has reserved sufficient shares of its Common Stock to satisfy the potential settlement of the warrants.

During 2014, $230.6 million principal amount of the Company's $400.0 million aggregate principal amount of Notes was surrendered for conversion, of which $220.6 million was settled prior to December 31, 2014. The Company 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 the Company's Common Stock in respect of any amounts due in excess thereof. Consequently, in 2014, the Company paid $220.6 million in cash and issued 2,017,732 shares of Common Stock. In addition, in 2014, the Company allocated $691.9 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholder's equity, and recognized a $33.5 million loss on the debt extinguishment.

During 2015, the Company settled conversion obligations for $166.5 million principal amount of the Company's Notes that was previously surrendered for conversion. In accordance with the terms of the Notes, the Company 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 the Company's Common Stock in respect of any amounts due in excess thereof. Consequently, in 2015, the Company paid $166.5 million in cash and issued 1,625,113 shares of Common Stock. In addition, in 2015, the Company allocated $819.7 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes and recognized such amount as a reduction of stockholders' equity, and recognized a $18.9 million loss on the debt extinguishment. As of December 31, 2015, an aggregate principal amount of $11.2 million of the original $400.0 million aggregate principal amount of Notes remained

outstanding.

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

	As of December 31,	
	2015	2014
Total convertible senior notes - par	$11,154	$169,400
Unamortized discount	(352)	(22,627)
	$10,802	$146,773

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The December 31, 2015 net carrying amount of the liability component of the Notes was recorded within other current liabilities within the Company's Balance Sheet since the Notes are due to mature on October 1, 2016.

Total interest expense associated with the Notes, net of capitalized interest as applicable (see Note 19), consists of the following:

	Year Ended December 31,		
	2015	2014	2013
Contractual coupon interest rate	$544	$5,036	$7,230
Amortization of discount and note issuance costs	2,818	17,821	22,980
	$3,362	$22,857	$30,210

As a result of the Note conversions described above, the Company also exercised a proportionate amount of its convertible note hedges during 2015 and 2014, for which the Company received 1,625,088 and 2,017,732 shares, respectively, of Common Stock, which was approximately equal to the number of shares the Company was required to issue to settle the non-cash portion of the related Note conversions. The Company recorded the cost of the shares received, or $136.5 million and $169.5 million, respectively, as Treasury Stock during 2015 and 2014.

Warrant Transactions

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties 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 the Company not to exceed $148.5 million. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did 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. The Company was obligated to settle any payments due under the amendment agreement in February 2015. Given that the amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the 493,229 warrants from additional paid-in capital to a liability in November 2014, with such liability subsequently measured at fair value with changes in fair value recognized in earnings. The change in fair value for the year ended December 31, 2014 resulted in the Company recording a gain of $1.2 million. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2014, the Company recorded a $59.8 million accrued liability as of December 31, 2014. The estimated fair value of the remaining liability as of December 31, 2014 was $87.5 million, and was recorded within other current liabilities within the Company's Balance Sheet. During the first quarter of 2015, the warrant holder closed out additional portions of its hedge position, and, as a result, in February 2015 the Company paid a total of $124.0 million to reduce the number of warrants held by such warrant holder by 416,480. Upon expiration of the November 2014 amended agreement, in the first quarter of 2015, the remaining warrants were re-measured at fair value, and $23.3 million was reclassified back to additional paid-in capital, consistent with the original classification of the warrants under the 2011 issuance. Total losses related to changes in fair value of the warrants during the first quarter of 2015 were not material.

During 2014, in addition to the November 2014 warrant agreement described above, the Company entered into agreements to reduce the number of warrants held by the warrant holders. Pursuant to the agreements, the Company 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 by 1,220,745 in the aggregate.

In November 2015, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 476,376. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $535.00 per share, during the period starting on November 16, 2015 and ending no later than

February 9, 2016. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2015, the Company paid a total of $50.0 million in 2015 to reduce the number of warrants it held by 115,970. Additionally, during January 2016, the warrant holder closed out additional portions of its hedge position, and, as a result, the Company paid a total of $135.3 million to further reduce the number of warrants held by such warrant holder by 360,406 (which was the remaining maximum number of warrants to be reduced subject to the amendment agreement).

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In addition to the warrant transactions described above, during 2015, the Company entered into other agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, the Company paid an aggregate amount of $399.5 million to the warrant holders during 2015 to reduce the number of shares of Common Stock issuable upon exercise of the warrant by 898,547 in the aggregate.

As of December 31, 2015, an aggregate of 2,109,098 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

b. Credit Facility

In March 2015, the Company entered into an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes an option for the Company to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for the Company to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty.

Any loans under the Credit Facility have a variable interest rate based on either the London Interbank Offered Rate ("LIBOR") or an alternate base rate, plus an applicable margin that varies with the Company's debt rating and total leverage ratio. The Company had no borrowings outstanding under the Credit Facility as of December 31, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. The Company was in compliance with all covenants of the Credit Facility as of December 31, 2015.

12. Commitments and Contingencies

a. Leases

Descriptions of Lease Agreements

The Company leases laboratory and office facilities in Tarrytown, New York. The facilities leased by the Company in Tarrytown include (i) space in previously existing buildings, (ii) newly constructed space in two buildings ("Buildings A and B") that was completed in 2009, (iii) newly constructed space in a third building ("Building C") that was completed in 2011 and, (iv) under an April 2013 lease agreement, newly constructed laboratory and office space in two buildings ("Buildings D and E") that was completed in the third quarter of 2015. The lease agreements related to Buildings A, B, C, D, and E (collectively, the "Buildings") will expire in 2029; the remaining facilities under lease will expire in June 2024. The Tarrytown leases contain renewal options to extend the term of the lease, escalations at 2.5% per annum, and early termination options for various portions of the space. The leases provide for monthly payments over their respective terms (which, for Buildings A, B, C, D, and E were largely based on the landlord's cost of construction and tenant allowances) and additional charges for utilities, taxes, and operating expenses.

Certain premises under the Tarrytown lease are accounted for as operating leases. However, as described further below under "Facility Lease Obligations," for the Buildings that the Company is leasing, the Company is deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of FASB authoritative guidance.

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

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Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under operating leases, as of December 31, 2015, are as follows:

	Facilities	Equipment	Total
2016	$10,894	$4,594	$15,488
2017	11,332	425	11,757
2018	11,607	140	11,747
2019	11,740	—	11,740
2020	11,375	—	11,375
Thereafter	50,746	—	50,746
	$107,694	$5,159	$112,853

Rent expense under operating leases was:

Year Ended December 31,	Facilities	Equipment	Total
2015	$14,659	$543	$15,202
2014	13,360	952	14,312
2013	9,404	471	9,875

In addition to its rent expense under operating leases for various facilities, the Company paid rental charges for utilities, real estate taxes, and operating expenses of $15.5 million, $13.6 million, and $11.5 million for the years ended December 31, 2015, 2014, and 2013, respectively.

Facility Lease Obligations

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

With respect to Buildings A and B, in 2009, monthly lease payments commenced and the buildings were placed in service by the Company. The imputed interest rate applicable to the Company's Buildings A and B facility lease obligation is approximately 11%. With respect to Building C, in 2011, monthly lease payments commenced and the building was placed in service by the Company. The imputed interest rate applicable to the Company's Building C facility lease obligation is approximately 10%. With respect to Buildings D and E, in 2015, monthly lease payments commenced and the buildings were placed in service by the Company. The imputed interest rate applicable to the Company's Buildings D and E facility lease obligation is approximately 7%. In 2015, 2014, and 2013, the Company recognized $9.7 million, $14.5 million, and $16.2 million, respectively, of interest expense in connection with the Buildings' facility lease obligations.

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Facility lease obligations consist of the following:

	As of December 31,	
	2015	2014
Buildings A and B	$108,857	$110,210
Building C	49,475	49,312
Buildings D and E	206,376	152,770
	$364,708	$312,292

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2015, are as follows:

	Buildings A and B	Building C	Buildings D and E	Total
2016	$13,809	$4,688	$12,679	$31,176
2017	14,079	4,818	13,016	31,913
2018	14,356	4,951	13,360	32,667
2019	14,640	5,088	13,714	33,442
2020	14,931	5,227	14,076	34,234
Thereafter	117,096	54,760	137,079	308,935
	$188,911	$79,532	$203,924	$472,367

b. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with other companies and universities. These agreements contain varying terms and provisions which include fees to be paid by the Company, services to be provided, and license rights to certain proprietary technology developed under the agreements. Some of these agreements may require the Company to pay additional amounts upon the achievement of various development and commercial milestones, contingent upon the occurrence of various future events. Additionally, some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.5% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements. The Company also has contingent reimbursement obligations to its collaborators Sanofi and Bayer HealthCare once the applicable collaboration becomes profitable. See Note 3 for additional information.

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

Effective May 17, 2013, the Company entered into an Amended and Restated Non-Exclusive License and Settlement Agreement with Genentech (the "Amended Genentech Agreement"), which amended the Original Genentech Agreement to include all sales of EYLEA worldwide and ended the litigation relating to those matters. Under the Amended Genentech Agreement, the Company received a worldwide non-exclusive license to the Davis-Smyth

patents, and certain other patents, owned or co-owned by Genentech for the prevention or treatment of eye diseases and eye disorders in a human through administration of EYLEA to the eye. Under

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the Amended Genentech Agreement, the Company is obligated to make payments to Genentech based on sales of EYLEA in the United States, and EYLEA manufactured in the United States and sold outside the United States, through May 7, 2016 using the same milestone and royalty rates as in the Original Genentech Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare under the Company's license and collaboration agreement. All payments to Genentech under the Original Genentech Agreement and the Amended Genentech Agreement have been or will be made by the Company. Bayer HealthCare shares 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.

The Company recognizes royalty expense based on product sales of commercial products under various licensing agreements, including, for EYLEA sales both inside and outside of the United States, the Genentech agreements described above. For the years ended December 31, 2015, 2014, and 2013, the Company recorded royalty expense of $247.9 million, $169.9 million, and $128.1 million, respectively.

13. Stockholders' Equity

The Company's Restated Certificate of Incorporation, as amended, provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 320 million shares of Common Stock (increased from 160 million shares effective upon shareholder approval obtained in 2015), par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the board of directors.

In December 2007, Sanofi purchased 12 million newly issued, unregistered shares of the Company's Common Stock. As a condition to the closing of this transaction, Sanofi entered into an investor agreement, as amended and restated in January 2014, with the Company. Under the terms of the amended and restated investor agreement, Sanofi has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock held by Sanofi from time to time. Under the amended and restated investor agreement, Sanofi has also agreed not to dispose of any shares of the Company's Common Stock beneficially owned by Sanofi from time to time until the later of (i) December 20, 2020, and (ii) the expiration of the Antibody Discovery Agreement with Sanofi, as amended (see Note 3a) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving the Company or the Company's dissolution or liquidation, and certain restrictions have been imposed on the manner of sales thereafter. Further, pursuant to the amended and restated investor agreement, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of the Company or acquiring more than 30% of the outstanding shares of the Company's Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Company's License and Collaboration Agreement with Sanofi and the Company's ZALTRAP Agreement with Sanofi, each as amended (see Note 3a) and (ii) other specified events. Sanofi has also agreed to vote as recommended by the Company's board of directors, except that it may elect to vote proportionally with the votes cast by all of the Company's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the

occurrence of certain events.

In addition, upon Sanofi reaching 20% ownership of the Company's then outstanding shares of Class A Stock and Common Stock (taken together) during 2014, the Company was required to appoint an individual agreed upon by the Company and Sanofi to the Company's board of directors. This individual is required to be independent of the Company, and not to be a current or former officer, director, employee, or paid consultant of Sanofi.

In October 2011, the Company completed a private placement of $400.0 million aggregate principal amount of Notes, which are convertible into shares of the Company's Common Stock. In connection with the offering of the Notes in October 2011, the Company entered into convertible note hedge and warrant transactions. During 2015 and 2014, a substantial portion of the Notes were surrendered for conversion. The Company elected to settle these conversion obligations through a combination of cash, in

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an amount equal to the principal amount of the converted Notes, and shares of the Company's Common Stock in respect of any amounts due in excess thereof. A portion of the settlement consideration provided to the Note holders was allocated to the reacquisition of the equity component of the Notes. In addition, as a result of the Note conversions, the Company exercised a proportionate amount of its convertible note hedges, for which the Company received shares of Common Stock. The shares received were recorded as Treasury Stock, at cost. See Note 11.

During 2015 and 2014, the Company entered into agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, the Company made payments to the warrant holders to reduce the maximum number of shares of Common Stock issuable upon the exercise of the warrants by warrant holders. In addition, in November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder. Given that the November 2014 amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the warrants from additional paid-in capital to a liability in November 2014. See Note 11.

In connection with the Company's January 2014 license and collaboration agreement with Bayer HealthCare for the joint development and commercialization outside the United States of antibody product candidates to PDGFR-beta (see Note 3b), Bayer HealthCare has also agreed to a "standstill" provision, which prohibits Bayer HealthCare and its affiliates from seeking to influence the control of the Company or acquiring more than 20% of the Company's then outstanding shares of Class A Stock and Common Stock (taken together).

14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated and approved by the Company's shareholders (the "2000 Incentive Plan"), provided for the issuance of up to 35,397,043 shares of Common Stock in respect of awards, in addition to any shares subject to awards that were returned to the 2000 Incentive Plan upon expiration, forfeiture, surrender, exchange, cancellation, or termination of previously granted awards.

During 2014, the Company established, and the Company's shareholders approved, the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "2014 Incentive Plan"). As of the shareholder approval date, the 2014 Incentive Plan provides for the issuance of up to 16,485,333 shares of Common Stock in respect of awards (including 4,485,333 shares of Common Stock rolled over into the 2014 Incentive Plan from the 2000 Incentive Plan), which were registered with the Securities and Exchange Commission, in addition to any shares subject to awards under the 2000 Incentive Plan or the 2014 Incentive Plan that are added to the pool of shares available for grant under the 2014 Incentive Plan upon the expiration, forfeiture, surrender, exchange, cancellation, or termination of previously granted awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors (collectively, "Participants"), may receive awards as determined by a committee of independent directors ("Committee").

The awards that may be made under the 2014 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price may not be less than the fair market value of a share of Common Stock on the date the option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three- to four-year period. The Committee also determines the expiration date of each option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan or 2014 Incentive Plan (collectively, the "Incentive Plans") is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as specified in the Incentive Plans, except as determined by the Committee in its discretion and subject to the applicable Incentive Plan documents, the ownership of any unvested Restricted Stock will be transferred to the Company. In such an event, the Company will be obligated to repay the Participant the amount, if any, paid by the Participant for such shares. In addition, if the Company requires a return of the Restricted Stock, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of Common Stock as determined by the Committee, equal to the sum of the fair market value of a

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share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Common Stock. Subject to the provisions of the 2014 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

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

As of December 31, 2015, there were 9,711,439 shares available for future grants under the 2014 Incentive Plan. No additional awards may be made under the 2000 Incentive Plan.

a. Stock Options

Transactions involving stock option awards during 2015 under the Company's Incentive Plans are summarized in the table below.

Stock Options:	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value (in thousands)
Outstanding as of December 31, 2014	21,506,260	$ 158.54		
2015: Granted	4,495,487	$ 537.29		
Forfeited	(318,952)	$ 292.14		
Expired	(363)	$ 92.20		
Exercised	(2,516,663)	$ 98.26		
Outstanding as of December 31, 2015	23,165,769	$ 236.75	6.82	$7,209,994,851
Vested and expected to vest as of December 31, 2015	22,635,728	$ 231.75	6.76	$7,156,754,651
Exercisable as of December 31, 2015	13,212,236	$ 103.67	5.23	$5,852,659,560

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2015, 2014, and 2013 was $1,031.6 million, $1,081.2 million, and $727.5 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

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The Company grants stock options with exercise prices that are equal to or greater than the average market price of the Company's Common Stock on the date of grant ("Market Price"). The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2015, 2014, and 2013. The fair value of each option granted under the Company's Incentive Plans during these periods was estimated on the date of grant using the Black-Scholes option-pricing model.

	Number of Options Granted	Weighted-Average Exercise Price	Weighted-Average Fair Value
2015:			
Exercise price equal to Market Price	4,495,487	$ 537.29	$ 181.65
2014:			
Exercise price equal to Market Price	3,913,368	$ 385.33	$ 140.38
2013:			
Exercise price equal to Market Price	3,937,989	$ 263.77	$ 104.90

For the years ended December 31, 2015, 2014, and 2013, the Company recognized $443.7 million, $306.1 million, and $193.4 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards. As of December 31, 2015, there was $962.6 million of stock-based compensation cost related to outstanding non-performance based stock options, net of estimated forfeitures, which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 2.0 years.

For the years ended December 31, 2014 and 2013, the Company recognized $4.1 million and $8.0 million, respectively, of non-cash stock-based compensation expense related to performance-based options. As of December 31, 2013, there were 770,250 performance-based options outstanding and unvested, which were issued in 2011, and fully vested during 2014. The Company has not issued any performance-based options since 2011 and there were no performance-based options that were unvested as of December 31, 2015.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2015, 2014 and 2013.

	2015		2014		2013	
Expected volatility	35	%	39	%	42	%
Expected lives from grant date	5.1 years		5.2 years		5.3 years	
Expected dividend yield	0	%	0	%	0	%
Risk-free interest rate	1.68	%	1.62	%	1.73	%

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors' option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

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b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the year ended December 31, 2015 is summarized below:

Restricted Stock:		Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2014		546,060	$115.26
2015:	Granted	27,520	$540.40
	Vested	(31,880)	$164.65
Outstanding as of December 31, 2015		541,700	$133.96

The Company recognized non-cash stock-based compensation expense from Restricted Stock awards of $15.3 million, $11.5 million, and $14.0 million in 2015, 2014, and 2013, respectively. As of December 31, 2015, there was $33.9 million of stock-based compensation cost related to unvested shares of Restricted Stock which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 2.1 years.

c. Revisions of Previously-Issued Financial Statements

During the first quarter of 2015, the Company determined that for certain stock option awards granted to an employee in prior periods, the incorrect requisite service period was utilized in determining the period over which the related compensation expense should have been recorded. Such awards were made as part of the Company's annual employee option grants in December of each applicable year. As a result, compensation expense for the years ended December 31, 2014 and 2013 was understated. These revisions consisted entirely of non-cash adjustments, and therefore had no impact on the Company's previously reported total cash flows from operating activities and total cash flows in its Statements of Cash Flows. The Company evaluated the impact of these items on prior periods, assessing materiality quantitatively and qualitatively, and concluded that the errors were not considered to be material to any previously-issued quarterly or annual financial statements. However, the Company concluded that it would revise the applicable prior period amounts in this filing to reflect the impact of these corrections because the cumulative amount of such corrections was expected to be material to the year ending December 31, 2015.

The tables below present the impact of these revisions, including the related tax effect, on the Company's previously-filed financial statements.

	December 31, 2014		
	As Previously Reported	Adjustments	As Revised
Balance Sheet Data:			
Deferred tax assets	$316,104	$22,152	$338,256
Total assets	3,871,827	22,152	3,893,979
Additional paid-in capital	2,404,118	60,890	2,465,008
Retained earnings	255,382	(38,738)	216,644
Total stockholders' equity	2,542,325	22,152	2,564,477
Total liabilities and stockholders' equity	3,871,827	22,152	3,893,979

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	Three Months Ended December 31, 2014 (Unaudited)		
	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Operations Data:			
Selling, general, and administrative	$143,743	$31,564	$175,307
Total operating expenses	554,962	31,564	586,526
Income from operations	247,367	(31,564)	215,803
Income before income taxes	221,287	(31,564)	189,723
Income tax expense	111,111	(11,483)	99,628
Net income	110,176	(20,081)	90,095
Net income per share - basic	$1.09	$(0.20)	$0.89
Net income per share - diluted	$0.96	$(0.18)	$0.78

	Year Ended December 31, 2014			Year Ended December 31, 2013		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Operations Data:						
Selling, general, and administrative	$504,755	$14,512	$519,267	$329,415	$16,978	$346,393
Total operating expenses	1,981,126	14,512	1,995,638	1,344,717	16,978	1,361,695
Income from operations	838,431	(14,512)	823,919	760,028	(16,978)	743,050
Income before income taxes	775,747	(14,512)	761,235	713,360	(16,978)	696,382
Income tax expense	427,673	(4,564)	423,109	288,998	(6,354)	282,644
Net income	348,074	(9,948)	338,126	424,362	(10,624)	413,738
Net income per share - basic	$3.46	$(0.10)	$3.36	$4.33	$(0.10)	$4.23
Net income per share - diluted	$3.07	$(0.09)	$2.98	$3.81	$(0.09)	$3.72

	Year Ended December 31, 2014			Year Ended December 31, 2013		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Cash Flows Data:						
Cash flows from operating activities						
Net income	$348,074	$(9,948)	$338,126	$424,362	$(10,624)	$413,738
Non-cash compensation expense	307,238	14,512	321,750	198,399	16,978	215,377
Deferred taxes	(66,604)	(4,564)	(71,168)	63,601	(6,354)	57,247

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15. Employee Savings Plans

The Company maintains the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan, as amended and restated, allow U.S. employees who are age twenty-one or older to contribute to the Savings Plan a percentage of their compensation. In addition, the Company may make discretionary contributions ("Contribution"), as defined, to the accounts of participants under the Savings Plan. The Company recognized $15.4 million, $13.1 million, and $5.7 million of Contribution expense in 2015, 2014, and 2013, respectively.

In 2014, the Regeneron Ireland Pension Plan (the "Ireland Plan"), a defined contribution occupational pension plan which covers all eligible Ireland-based employees (as defined by the Ireland Plan), was established. Contributions to the Ireland Plan are comprised of two components: (i) a minimum mandatory employee and employer contribution rate, and (ii) a matching scheme, whereby the Company will match employee contributions up to a certain percentage. Employees can make additional voluntary contributions to the Ireland Plan. Expenses related to the Company's contributions to the Ireland Plan were not material during 2015 and 2014.

16. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. Components of income before income taxes consist of the following:

	Year Ended December 31,		
	2015	2014	2013
United States	$1,665,087	$1,101,446	$795,300
Foreign	(439,990)	(340,211)	(98,918)
	$1,225,097	$761,235	$696,382

Components of income tax expense consist of the following:

	Year Ended December 31,		
	2015	2014	2013
Current:			
Federal	$686,561	$437,038	$196,527
State	28,568	28,718	23,489
Foreign	4,004	2,879	433
Total current tax expense	719,133	468,635	220,449
Deferred:			
Federal	(119,849)	(62,932)	53,504
State	(3,768)	18,891	8,700
Foreign	(6,475)	(1,485)	(9)
Total deferred tax (benefit) expense	(130,092)	(45,526)	62,195
	$589,041	$423,109	$282,644

In 2015, 2014, and 2013, the Company utilized $405.3 million, $439.3 million, and $211.9 million of excess tax benefits in connection with stock option exercises, which were credited to additional paid-in capital as realized.

The Company also recorded an income tax provision in its Statement of Comprehensive Income of $24.9 million and $27.1 million during the years ended December 31, 2015 and 2014, respectively, in connection with unrealized gains (losses) on "available-for-sale" marketable securities. For the year ended December 31, 2013, no such income tax provision or benefit was recognized.

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

	Year Ended December 31,		
	2015	2014	2013
U.S. federal statutory tax rate	35.0 %	35.0 %	35.0 %
State and local income taxes	1.0	2.4	3.4
Change in state effective rate	(0.1)	2.9	—
Foreign income tax rate differential	12.2	15.8	4.9
Income tax credits	(1.6)	(5.1)	(4.9)
Non-deductible Branded Prescription Drug Fee	2.0	2.8	1.1
Domestic production activities deduction	(3.2)	—	—
Other permanent differences	2.8	1.8	1.1
Effective income tax rate	48.1 %	55.6 %	40.6 %

In 2015, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 48.1% is primarily attributable to losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, partly offset by the positive impact of the domestic manufacturing deduction.

In 2014, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 55.6% was primarily attributable to losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-deductible Branded Prescription Drug Fee, partly offset by the positive impact of the federal tax credit for increased research activities and state income tax credits.

In 2013, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 40.6% was primarily attributable to increases related to losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and state and local taxes. These negative impacts were partially offset by federal and state income tax credits. In January, 2013, The American Taxpayer Relief Act was enacted, which included a provision to extend the income tax credit for increased research activities retroactively to the tax year ended December 31, 2012, as well as for 2013. As a result of the extension, during 2013, the Company recognized the benefit of both the 2012 and 2013 federal research tax credit, which totaled $34.0 million.

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

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	As of December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforward	$140	$150
Fixed assets	—	8,078
Deferred revenue	51,766	60,223
Deferred compensation	349,508	216,640
Income tax credit carryforwards	—	8,539
Capitalized research and development costs	7,725	12,908
Accrued expenses	47,520	19,331
Other	26,580	21,922
	483,239	347,791
Valuation allowance	—	(359)
Total deferred tax assets	483,239	347,432
Deferred tax liabilities:		
Unrealized gains/losses on marketable securities	(3,280)	(28,186)
Fixed assets	(5,559)	—
Convertible senior notes	—	(252)
Other	(12,455)	(3,578)
Total deferred tax liabilities	(21,294)	(32,016)
Net deferred tax assets	$461,945	$315,416

The Company has state net operating loss carryforwards and state tax credits which will expire in various years from 2024 to 2034. The Internal Revenue Code and various state tax laws contain certain provisions that can limit a taxpayer's ability to utilize net operating losses and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50% over a three-year period. The Company does not believe, however, that any such limitation would have a significant impact on the Company's ability to utilize its net operating losses or income tax credit carryforwards prior to expiration.

The Company's 2012 through 2014 federal income tax returns remain open to examination by the IRS. The Company's 2012 federal income tax return is currently under audit by the IRS. The Company's state income tax returns from 2012 to 2014 remain open to examination. New York State Department of Taxation and Finance is currently auditing the Company's 2012 through 2014 tax returns, and the Department of Revenue of the Commonwealth of Pennsylvania is currently auditing the Company's 2013 and 2014 tax returns. The United States and many states generally have statutes of limitation ranging from 3 to 5 years; however, those statutes could be extended due to the Company's net operating loss and tax credit carryforward positions in a number of the Company's tax jurisdictions. In general, tax authorities have the ability to review income tax returns for loss periods in which the statute of limitation has previously expired to adjust the net operating loss carryforward or tax credits generated in those years.

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The following table summarizes the gross amounts of unrecognized tax benefits. The amount of unrecognized tax benefits that, if settled, would impact the effective tax rate is $102.1 million, $51.2 million, and $23.5 million as of December 31, 2015, 2014, and 2013, respectively.

	2015	2014	2013
Balance as of January 1	$57,615	$26,627	$11,274
Gross increases related to current year tax positions	59,909	27,538	7,620
Gross (decreases) increases related to prior year tax positions	(952)	6,464	8,305
Gross decrease due to settlements, recapture, filed returns, and lapse of statutes of limitation	—	(3,014)	(572)
Balance as of December 31	$116,572	$57,615	$26,627

In 2014 and 2015, the increases in unrecognized tax benefits related primarily to the Company's calculation of certain tax credits and other items related to the Company's international operations. In 2014, the decreases in unrecognized tax benefits resulted from the settlement of the IRS audit of the 2011 tax year and the New York State audit of the 2009 to 2011 tax years, as well as the reduction in the New York state income tax rate. In 2013, the increase in unrecognized tax benefits related primarily to the Company's calculation of certain tax credits. In 2015, the Company accrued interest of $1.2 million related to its unrecognized tax benefits. In 2014, accrued interest related to unrecognized tax benefits recorded by the Company was not material, and no interest was accrued in 2013. The Company believes that it is reasonably possible that its unrecognized tax benefits at December 31, 2015 may increase within the next twelve months relating to operations during that period, in excess of potential decreases due to the resolution of the federal audit.

17. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

Proceedings Relating to '287 Patent, '018 Patent, and '163 Patent

The Company is a party to patent infringement litigation initiated by the Company involving its European Patent No. 1,360,287 (the "'287 Patent), its European Patent No. 2,264,163 (the "'163 Patent), and its U.S. Patent No. 8,502,018 (the "'018 Patent"). Each of these patents concerns genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings, the Company claims infringement of several claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable). At this time, the Company is not able to predict the outcome of, or an estimate of gain or a range of possible loss, if any, related to, these proceedings.

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Proceedings Relating to Praluent (alirocumab) Injection

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 prohibit Regeneron 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, which Regeneron is 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 (the "'165 Patent"), and 8,859,741 (the "'741 Patent") in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 (the "'914 Patent") 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. On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint, which was granted on January 29, 2016. As amended, the complaint alleges, among other things, willful infringement of the asserted patents, which would allow the court to increase damages up to three times the amount assessed if the court finds willful infringement. On October 20, 2015, the District Court issued its claim construction order, in which it defined the meaning of certain disputed claim terms; none of the court's rulings were dispositive of the issues in the case. On November 3, 2015, pursuant to court order, the patents asserted by Amgen were narrowed to the '165, '741, and '914 Patents. The trial is currently set to begin on March 7, 2016, and a permanent injunction hearing (which would be held if the court finds infringement of a valid patent claim by the Company and Sanofi) is currently scheduled to begin on March 23, 2016. At this time, the Company is not able to estimate a range of possible loss, if any, related to these proceedings.

Proceedings Relating to Patents Owned by Genentech and City of Hope

On July 27, 2015, the Company and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Western Division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent (alirocumab), of U.S. Patent No. 7,923,221 (the "'221 Patent") jointly owned by Genentech, Inc. ("Genentech") and City of Hope relating to the production of recombinant antibodies by host cells. On the same day, the Company and Sanofi-Aventis U.S. LLC initiated an inter partes review in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of certain claims of U.S. Patent No. 6,331,415 jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies by host cells. On February 5, 2016, the USPTO instituted an inter partes review of the validity of most of the patent claims for which review had been requested. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by the Company and Sanofi in the District Court and counterclaimed, alleging that the Company and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016. At this time, the Company is not able to predict the outcome of, or an estimate of gain or range of possible loss, if any, related to these proceedings.

Proceedings Relating to Shareholder Derivative Claims

On December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former non-employee members of the Company's board of directors, the Chairman of the board of directors, the Company's Chief Executive Officer, and the Company's Chief Scientific Officer as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2013 and 2014. The complaint seeks damages in favor of the Company for the alleged breaches of fiduciary duties and unjust enrichment; changes to Regeneron's corporate governance and internal procedures;

invalidation of the 2014 Incentive Plan with respect to the individual defendants' compensation and a shareholder vote regarding the individual defendants' equity compensation; equitable relief, including an equitable accounting with disgorgement; and award of the costs of the action, including attorneys' fees. The Company intends to move to dismiss the shareholder derivative complaint.

On or about December 15, 2015, the Company received a shareholder litigation demand upon the Company's board of directors made by a purported Regeneron shareholder. The demand asserts that the current and certain former non-employee members of the board of directors and the Chairman of the board of directors excessively compensated themselves in 2013 and 2014. The demand requests that the board of directors investigate and bring legal action against these directors for breach of fiduciary duty, unjust enrichment, and corporate waste, and implement internal controls and systems designed to prohibit and prevent similar actions in the future. The Company's board of directors, working with outside counsel, investigated the allegations in the demand

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and the shareholder derivative complaint, and has determined to defer its decision on the demand until the court rules on the forthcoming motion to dismiss the shareholder derivative complaint, as discussed above.

At this time, the Company is not able to estimate a range of possible loss, if any, relating to these matters.

18. Net Income Per Share

The Company's basic net income per share amounts have been computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	Year Ended December 31,		
	2015	2014	2013
Net income - basic and diluted	$636,056	$338,126	$413,738
(Shares in thousands)			
Weighted average shares - basic	103,061	100,612	97,917
Effect of dilutive securities:			
Stock options	9,446	9,440	10,233
Restricted stock	477	425	433
Warrants	2,246	2,936	2,707
Dilutive potential shares	12,169	12,801	13,373
Weighted average shares - diluted	115,230	113,413	111,290
Net income per share - basic	$6.17	$3.36	$4.23
Net income per share - diluted	$5.52	$2.98	$3.72

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive, include the following:

	Year Ended December 31,		
(Shares in thousands)	2015	2014	2013
Stock options	1,343	1,470	304
Convertible senior notes	994	4,247	4,761

19. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities:

Included in accounts payable and accrued expenses as of December 31, 2015, 2014, and 2013 were $50.7 million, $56.2 million, and $16.1 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses as of December 31, 2015 and 2014 was $1.6 million and $7.5 million, respectively, for the Company's conversion settlement obligation related to the Company's Notes which were surrendered for conversion but not settled as of the end of the respective period. No such amounts were payable as of December 31, 2013.

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Included in accounts payable and accrued expenses as of December 31, 2014 was $59.8 million related to the Company's payment obligation for a reduction in the number of warrants based on a warrant holder closing out a portion of its hedge position (see Note 11). Additionally, included within other current liabilities as of December 31, 2014 was $87.5 million in connection with the estimated fair value of the remaining warrant liability (see Note 11). There were no such liabilities recorded in connection with warrants as of December 31, 2015 and 2013.
The Company recognized a facility lease obligation of $26.0 million, $127.8 million and $25.0 million during 2015, 2014 and 2013, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased (see Note 12a).

20. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2015 and 2014 are set forth in the following tables.

	First Quarter Ended March 31, 2015	Second Quarter Ended June 30, 2015	Third Quarter Ended September 30, 2015	Fourth Quarter Ended December 31, 2015
	(Unaudited)			
Revenues	$869,612	$998,617	$1,137,422	$1,098,077
Net income	$76,021	$194,643	$210,398	$154,994
Net income per share - basic	$0.74	$1.89	$2.04	$1.49
Net income per share - diluted	$0.66	$1.69	$1.82	$1.34

	First Quarter Ended March 31, 2014*	Second Quarter Ended June 30, 2014*	Third Quarter Ended September 30, 2014*	Fourth Quarter Ended December 31, 2014*
	(Unaudited)			
Revenues	$625,740	$665,700	$725,788	$802,329
Net income [(1)]	$68,305	$96,351	$83,375	$90,095
Net income per share - basic	$0.69	$0.96	$0.83	$0.89
Net income per share - diluted	$0.61	$0.85	$0.73	$0.78

* Certain revisions have been made to the amounts originally reported for quarterly periods ended March 31, June 30, September 30, and December 31, 2014. See Note 14.
(1) Net income in the third quarter of 2014 included a $40.6 million incremental charge related to the Branded Prescription Drug Fee based on final regulations issued by the IRS in July 2014 as described in Note 2 above.