

REGENERON PHARMACEUTICALS INC  
Form 10-K  
February 09, 2017

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

FORM 10-K

(Mark One)

ANNUAL  
REPORT  
PURSUANT  
TO SECTION

13 OR 15(d)

OF THE  
SECURITIES  
EXCHANGE  
ACT OF 1934

For the fiscal  
year ended  
December 31,  
2016

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

(State or other jurisdiction of incorporation or organization)

777 Old Saw Mill River Road, Tarrytown, New York

(Address of principal executive offices)

(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

13-3444607

(I.R.S. Employer Identification No.)

10591-6707

(Zip Code)

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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 filer a Accelerated filer Non-accelerated filer Smaller reporting company  
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No a

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$35,224,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2016, 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 1, 2017:

Class of Common Stock	Number of Shares
Class A Stock, \$.001 par value	1,911,456
Common Stock, \$.001 par value	104,169,299

**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 85 to 92 of this filing.

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"ARCALYST®", "EYLEA®", "ZALTRAP®", "VelocImmune®", "VelociGene®", "VelociMouse®", "VelociMab®", and "VelociSuite®" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners.



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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 EYLEA<sup>®</sup> (aflibercept) Injection, Praluent<sup>®</sup> (alirocumab) Injection, sarilumab, Dupixent<sup>®</sup> (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 EYLEA, Praluent, sarilumab, Dupixent, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA 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, as well as actions by our collaborators or third-party manufacturers, or other parties performing steps in the supply chain, impacting the foregoing; 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 changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), 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, including without limitation the patent litigation relating to Praluent described further in Part I, Item 3. "Legal Proceedings" of this report. 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 rheumatoid arthritis (RA), asthma, atopic dermatitis, pain, cancer, and infectious diseases.

Our significant 2016 business highlights include:

EYLEA (aflibercept) Injection, which is approved by the U.S. Food and Drug Administration (FDA) for use in retinal indications, delivered U.S. net sales growth of 24.2% over 2015, and continues to be the market-leading, branded anti-VEGF therapy in the United States. A Phase 3 study for the treatment of non-proliferative diabetic retinopathy (NPDR) in patients without DME was initiated.

• We, along with our partner Sanofi, received regulatory approval for Praluent in additional countries outside the United States. Praluent has been launched in the United States, Europe, and other countries. We also reported positive Phase

3 data from the ODYSSEY ESCAPE study of Praluent in patients with heterozygous familial hypercholesterolemia (HeFH) and consequently, high LDL cholesterol levels who were undergoing apheresis. A Phase 3 cardiovascular outcomes study of Praluent is ongoing.

We reported positive efficacy and safety data from Phase 3 studies of Dupixent in patients with moderate-to-severe atopic dermatitis. The FDA accepted, and granted priority review for, the Biologics License Application (BLA) for Dupixent for the treatment of atopic dermatitis with a target action date of March 29, 2017. In addition, the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for Dupixent for the treatment of atopic dermatitis. The FDA granted Breakthrough Therapy designation for Dupixent for the treatment of atopic dermatitis

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in pediatric patients. A Phase 3 study of dupilumab for the treatment of uncontrolled, persistent asthma completed enrollment. A Phase 3 study of dupilumab for the treatment of nasal polyps was also initiated.

A Phase 3 study of fasinumab in patients with pain due to osteoarthritis of the knee or hip was initiated. A Phase 2b study of fasinumab in chronic low back pain was also initiated and later placed on clinical hold by the FDA. We completed an unplanned analysis of this Phase 2b study in chronic low back pain which showed clear evidence of efficacy with improvement in pain scores in all fasinumab groups compared to placebo.

REGN2810 entered a potentially pivotal clinical study for the treatment of advanced cutaneous squamous cell carcinoma.

Phase 2 studies of EYLEA, in a co-formulated combination with nesvacumab, an antibody to angiopoietin-2 (ANG2), advanced in clinical development for the treatment of wet AMD and DME.

We advanced four new product candidates (REGN3500, REGN3470-3471-3479, REGN2477, and REGN3767) into Phase 1 clinical development.

We entered into significant new research and development license and collaboration arrangements: a collaboration with Bayer for a co-formulated combination therapy of the Ang2 antibody nesvacumab and aflibercept for the treatment of serious eye diseases; a collaboration with Teva for fasinumab; a license and collaboration with Intellia Therapeutics, Inc. to advance CRISPR/Cas gene-editing technology for in vivo therapeutic development; and a license and collaboration agreement with Adicet Bio, Inc. to develop next-generation engineered immune-cell therapeutics with fully human chimeric antigen receptors and T-cell receptors directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells.

Our initiatives in genomics also advanced, and we have sequenced over 150,000 exomes to date.

From a company growth perspective, we hired our 5,000<sup>th</sup> employee, purchased an office building near our Tarrytown facility, purchased land and an office building near our Rensselaer, New York facilities, 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 the top employer in the global biotech and pharmaceutical industry by Science magazine. We have been ranked first for four of the past six years, with second place rankings in 2015 and 2011.

Society for Science & the Public announced that Regeneron has become the new title sponsor of the Science Talent Search. Regeneron became only the third sponsor in 75 years of the nation's oldest and most prestigious high school science competition.

Our total revenues were \$4,860.4 million in 2016, compared to \$4,103.7 million in 2015 and \$2,819.6 million in 2014. Our net income was \$895.5 million, or \$7.70 per diluted share, in 2016, compared to \$636.1 million, or \$5.52 per diluted share, in 2015, and \$338.1 million, or \$2.98 per diluted share, in 2014. 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 five products that have received marketing approval:

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 the EU, Japan, and certain other countries outside the United States for the treatment of myopic choroidal neovascularization (mCNV) and in the United States for the treatment of diabetic retinopathy in patients with DME. Bayer has additional regulatory applications for EYLEA for various indications pending in other countries. We are collaborating with Bayer on the 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.

Praluent is also available in certain countries in Europe 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. In July 2016, the Japanese Ministry of Health, Labour and Welfare (MHLW) granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk. 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. See Part I, Item 3. "Legal Proceedings" for information regarding the patent infringement proceedings relating to Praluent, which may impact Praluent's commercial availability in the United States and other jurisdictions.

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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.

Kevzara™ (sarilumab) Solution for Subcutaneous Injection. In January 2017, Health Canada approved Kevzara for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have an inadequate response to or intolerance to one or more biologic or non-biologic disease modifying anti-rheumatic drugs (DMARDs). This is the first approval of Kevzara worldwide.

ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, known in the scientific literature as VEGF Trap, which is available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. Pursuant to a 2015 amended and restated ZALTRAP agreement (Amended ZALTRAP Agreement), Sanofi is solely responsible for the development and commercialization of ZALTRAP, and Sanofi pays us a percentage of aggregate net sales of ZALTRAP.

We have 16 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 15 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune® technology.

Trap-based Clinical

Program

EYLEA

Phase 3 study for the treatment of

Neovascular Glaucoma

(NVG) (in Japan) was

completed in 2016 (in

collaboration with

Bayer). Phase 3 study

for the treatment of

non-proliferative

diabetic retinopathy in

patients without DME

initiated in the first

quarter of 2016. As

described below,

aflibercept is also being

studied in combination

with nesvacumab, 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.

Sarilumab (REGN88)

Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2). Phase 2 study in Polyarticular-course Juvenile Idiopathic Arthritis (pcJIA) initiated in the third quarter of 2016.

Dupixent

(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 in adults and adolescents (Phase 3), and eosinophilic esophagitis (EoE) (Phase 2). Phase 3 study in patients with nasal polyps initiated in the fourth quarter of 2016.

REGN2810

Antibody to programmed cell death protein 1 (PD-1). In Phase 1 clinical development in solid tumors and advanced hematologic malignancies.

Potentially pivotal Phase 2 study for the treatment of advanced cutaneous squamous cell carcinoma initiated in the second quarter of 2016. REGN 2810 is also being studied in combination with other

antibodies and  
treatments.

REGN3500

Antibody to  
interleukin-33 receptor  
(IL-33) being developed  
for inflammatory  
diseases. Phase 1 study  
in healthy volunteers  
initiated in the third  
quarter of 2016. Phase 1  
study in patients with  
mild asthma initiated in  
the first quarter of 2017.

REGN3767

Antibody to  
Lymphocyte Activation  
Gene 3 (LAG-3)  
protein. Phase 1 study  
(administered alone or  
in combination with  
REGN2810) in  
advanced malignancies  
initiated in the fourth  
quarter 2016.

Antibody-based  
Clinical Program in  
Collaboration with

Bayer

Nesvacumab/aflibercept  
(REGN910-3)\*\*

Combination product  
comprised of an  
antibody to Ang2  
co-formulated with  
aflibercept for  
intravitreal injection for  
use in ophthalmology.

Phase 2 studies for the  
treatment of wet AMD  
and DME initiated in  
the first quarter of 2016.

Fast track designation  
received from the FDA  
for the treatment of  
patients with wet AMD,  
DME and diabetic  
retinopathy.

Antibody-based  
Clinical Program in  
Collaboration with Teva

and Mitsubishi Tanabe  
Pharma  
Fasinumab  
(REGN475)\*  
Antibody to Nerve  
Growth Factor (NGF).  
Phase 3 long-term  
safety and efficacy  
study in patients with  
osteoarthritis of knee  
and hip initiated in the  
first quarter of 2016.  
Phase 2b study for  
chronic low back pain  
initiated in the first  
quarter of 2016, and  
placed on clinical hold  
by the FDA in October  
2016.

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Antibody-based Clinical Programs Developing Independently  
REGN2222\*  
Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. In Phase 3 clinical development for prevention of RSV infection.  
Evinacumab (REGN1500)\*  
Antibody to Angptl-3. In Phase 2 clinical development for the treatment of homozygous familial hypercholesterolemia (HoFH) and severe forms of hyperlipidemia. FDA granted orphan drug designation for the treatment of HoFH.  
Trevogrumab (REGN1033)\*  
Antibody to myostatin (GDF8). Phase 2 monotherapy study in patients with sarcopenia completed. REGN1033 is being studied in combination with REGN2477.  
REGN1908-1909\*  
Antibody to Feld1. In Phase 1 clinical development for the treatment of allergic disease.  
REGN1979  
Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia,

and Acute Lymphoblastic Leukemia. REGN1979 is also being studied in combination with REGN2810 in B-cell malignancies.

REGN3470-3471-3479\*\*\*

Antibody to Ebola virus. Phase 1 study in healthy volunteers initiated in the second quarter of 2016.

Also in the second quarter of 2016, the FDA granted orphan drug designation for the treatment of Ebola virus infection.

REGN2477\*

Antibody to Activin A being developed for Fibrodysplasia Ossificans Progressiva (FOP). Phase 1 study in combination with REGN1033 in healthy volunteers initiated in the second quarter of 2016. FDA granted orphan drug designation for the treatment of FOP.

\* 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 Ang2 receptor and ligand in ophthalmology

were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate and a potential development milestone.

\*\*\* Sanofi did not opt-in to the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate. In 2015, we and the Biomedical Advanced Research Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) entered into an agreement whereby HHS provides certain funding to support

research,  
development,  
and  
manufacturing  
of a  
monoclonal  
antibody  
therapy for the  
treatment of  
Ebola virus  
infection.

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.



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Marketed Products

EYLEA (afibercept) 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 and macular edema following RVO in 2014, and diabetic retinopathy in patients with DME in 2015. Outside the United States, Bayer commenced sales of EYLEA for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, and visual impairment due to DME and mCNV (in Japan) in 2014. In 2015, the European Commission and the Japanese Ministry of Health, Labour and Welfare (MHLW) approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. In addition, the European Commission approved EYLEA for the treatment of visual impairment due to mCNV in 2015. Bayer has additional regulatory applications for EYLEA for various indications pending in other countries, including EYLEA for the treatment of wet AMD in China.

We are collaborating with Bayer on the global development and commercialization of EYLEA outside the United States. Bayer 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 \$3,323.1 million in 2016, compared to \$2,676.0 million in 2015 and \$1,736.4 million in 2014. Bayer records net product sales of EYLEA outside the United States, which were \$1,872.3 million in 2016, compared to \$1,413.3 million in 2015 and \$1,038.5 million in 2014.

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 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. In July 2016, the Japanese Ministry of Health, Labour and Welfare (MHLW) granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk. In November 2016, the European Commission approved a Praluent dosing regimen of 300 milligrams (mg) every 4 weeks. 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. See Part I, Item 3. "Legal Proceedings" for information regarding the patent infringement proceedings relating to Praluent, which may impact Praluent's commercial availability in the United States and other jurisdictions.

Under our antibody 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 and thus far have not exercised our option to co-promote Praluent outside the United States. We and Sanofi share profits and losses from sales of Praluent. In 2016, net product sales of Praluent in the United States were \$94.4 million and net product sales of Praluent outside of the United States were \$21.9 million. In 2015, net product sales of Praluent in the United States were \$9.5 million and net product sales of Praluent outside of the United States were \$1.0 million.

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 \$15.3 million in 2016, \$13.5 million in 2015, and \$14.4 million in 2014.



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### Clinical Programs - Ophthalmologic Diseases

#### 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 2015, Bayer 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. The primary endpoint of this Phase 3 study (n=54), which was the change in IOP from baseline to week 1, was numerically in favor of EYLEA (p=0.06). Statistically significant improvements were observed in both neovascularization of the iris and neovascularization of the iridocorneal angle with EYLEA, compared to sham treatment. Most ocular treatment emergent adverse events were injection related, including conjunctival hemorrhage and injection site pain in the EYLEA group.

##### Diabetic Retinopathy

Diabetic retinopathy is a complication of diabetes mellitus characterized by microvascular damage to the blood vessels in the retina. It can progress to proliferative diabetic retinopathy (PDR), where new, abnormal vessels that are susceptible to hemorrhage grow initially from the retina and/or optic disc and extend beyond the internal limiting membrane. PDR can subsequently lead to various vision-threatening complications such as vitreous hemorrhage, traction macular detachment, and neovascular glaucoma. There is currently no standard treatment for non-proliferative diabetic retinopathy (NPDR) in the absence of DME and patients are often observed until disease progresses sufficiently to warrant intraocular surgery (vitrectomy) or, more commonly, extensive laser treatment (panretinal photocoagulation (PRP)). PRP is utilized with the intent of preserving function of the central retina, but is inherently destructive to the peripheral retina and may result in a considerable loss of peripheral visual field.

In the first quarter of 2016, a Phase 3 trial (PANORAMA) was initiated to assess the efficacy and safety of intravitreal aflibercept in patients with moderately severe to severe NPDR without DME.

##### Combination Product with Rinucumab

We have recently discontinued the Phase 2 CAPELLA study, evaluating aflibercept co-formulated with rinucumab in patients with wet AMD. The data from the study showed that at 12 and 28 weeks, the combination therapy did not add to the improvement in best corrected visual acuity (BCVA) that was demonstrated with intravitreal aflibercept

injection monotherapy, the primary endpoint of the study. Results in the EYLEA monotherapy arm of this study were consistent with the efficacy and safety observed in Phase 3 pivotal studies of EYLEA in wet AMD.

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### Combination Product with Nesvacumab

In the first quarter of 2016, two Phase 2 studies, RUBY (for the treatment of DME) and ONYX (for the treatment of wet AMD), were initiated. Both studies are investigating nesvacumab, an antibody to Ang2 co-formulated with aflibercept, as a single, intravitreal injection. Efficacy and safety data from both the RUBY and ONYX studies will be analyzed at week 36.

### 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, which is intended to lower LDL cholesterol.

##### Clinical Programs

**Phase 3 ODYSSEY Program.** 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. All patients who entered the ODYSSEY OUTCOMES trial had experienced a heart attack or unstable angina requiring hospitalization within the previous year before entering the trial, and experienced inadequately controlled LDL cholesterol despite receiving maximally-tolerated statins and potentially other lipid-lowering therapies.

In the first quarter of 2016, an independent Data Monitoring Committee (DMC) of the ODYSSEY OUTCOMES study completed the first interim analysis. In accordance with the protocol, the DMC performed a futility assessment. The DMC recommended the study continue with no changes. In the fourth quarter of 2016, an independent DMC conducted a second, pre-specified interim analysis for futility and overwhelming efficacy (hazard ratio <0.802 corresponding to  $p < 0.0001$ ) for the primary endpoint with consistency across subgroups and regions, positive trends for secondary end points including all-cause mortality, and no excess non cardiovascular mortality. Based on the recommendation of the independent DMC, the ODYSSEY OUTCOMES trial will continue as planned. Regeneron remains blinded to the actual results of the first and second interim analyses, and the DMC will continue to monitor the ongoing safety and efficacy of Praluent as planned.

In the first quarter of 2016, we and Sanofi announced positive results from the Phase 3 ODYSSEY ESCAPE trial evaluating Praluent in patients with HeFH, whose cholesterol levels required chronic, weekly or bi-weekly apheresis therapy. The trial met its primary endpoint, demonstrating that patients who added Praluent to their existing treatment regimen significantly reduced the frequency of their apheresis therapy by 75%, compared to placebo ( $p < 0.0001$ ). Sixty-three percent of patients treated with Praluent no longer required apheresis, compared to zero percent of placebo patients. Apheresis is a procedure where bad (LDL) cholesterol is removed from the blood, in a process similar to kidney dialysis.

In the third quarter of 2016, we and Sanofi announced, and presented at the ESC Congress 2016, additional positive detailed results from the Phase 3 ODYSSEY ESCAPE trial. The trial demonstrated that adding Praluent to existing therapy reduced LDL cholesterol by approximately 50% from baseline (compared to 2% increase for placebo). Other key results from ODYSSEY ESCAPE, which were also published in the *European Heart Journal*, included:

¶Ninety-three percent of patients treated with Praluent experienced at least a 50% reduction in their apheresis procedures ( $p < 0.0001$ ).

¶Throughout the trial, patients treated with Praluent experienced significant reductions in their LDL cholesterol starting

at week 6 (55% greater reduction compared to placebo), and lasting until the trial ended, at week 18 (46% greater reduction compared to placebo) ( $p < 0.0001$ ).

A similar proportion of patients experienced adverse events (AEs) in both the Praluent and placebo groups (76% in both groups). The most common AEs (occurring in at least 5% of the Praluent group) were fatigue (15% Praluent; 10% placebo), nasopharyngitis (10% Praluent; 10% placebo), diarrhea (10% Praluent; 0% placebo), myalgia (10% Praluent; 5% placebo), upper respiratory infection (7% Praluent; 19% placebo), headache (7% Praluent; 5% placebo), arthralgia (7% Praluent; 10% placebo), and back pain (5% Praluent; 10% placebo).

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In the second quarter of 2016, the FDA accepted for review a supplemental BLA for a monthly dosing regimen of Praluent, with a target action date of January 24, 2017. In January 2017, the FDA extended the review period for the supplemental BLA. The FDA determined that Regeneron's and Sanofi's responses to information requested by the FDA during its review of the sBLA was a major amendment, which has resulted in a three month extension of the Prescription Drug User Fee Act (PDUFA) date to allow time for the FDA to review the additional information. The new target action date is April 24, 2017.

In the fourth quarter of 2016, as a post-marketing commitment to the FDA, a Phase 4 randomized, placebo-controlled, long-term trial that prospectively evaluates the effect of Praluent on neurocognitive function was initiated.

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 Program. Based on positive results from the Phase 3 studies of sarilumab in adult patients with active RA, we and Sanofi submitted a BLA for U.S. regulatory approval of sarilumab, which was accepted for review by the FDA in December 2015. The target date for an FDA decision on the BLA was October 30, 2016. However, on October 28, 2016, we and Sanofi announced that the FDA issued a Complete Response Letter (CRL) regarding the BLA for sarilumab. The CRL refers to certain deficiencies identified during a routine good manufacturing practice inspection of the Sanofi facility in Le Trait, France where sarilumab is filled and finished, one of the last steps in the manufacturing process. Satisfactory resolution of these deficiencies is required before the BLA can be approved. The CRL did not identify any concerns relating to the safety or efficacy of sarilumab. The FDA subsequently reclassified the Sanofi Le Trait fill-and-finish facility as "acceptable" based on review of responses to an FDA Form 483, as well as proposed corrective actions. In the first quarter of 2017, we expect to resubmit the sarilumab BLA, contingent upon successful completion of the pre-approval inspection of Le Trait in connection with the Dupixent BLA. The sarilumab active pharmaceutical ingredient is manufactured by Regeneron at its Rensselaer, New York facility. The FDA has completed a pre-approval inspection of Regeneron's sarilumab manufacturing facility; no Form 483 was issued in connection with the pre-approval inspection of Regeneron's facility, which is the form used if the FDA investigators have observed any conditions that in their judgement may constitute a violation of the Food, Drug, and Cosmetic Act and related acts.

In July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for sarilumab. In addition, in October 2016, an application for marketing approval for sarilumab was submitted in Japan.

In March 2016, we and Sanofi announced positive top-line data from the Phase 3 SARIL-RA-MONARCH study that demonstrated superiority of sarilumab vs. adalimumab (marketed by AbbVie Inc. as HUMIRA<sup>®</sup>) in improving signs and symptoms of RA at 24 weeks in patients with active rheumatoid arthritis. The primary endpoint was change from baseline in DAS28-ESR at 24 weeks, which demonstrated a statistically significant difference in favor of sarilumab (-3.25 for sarilumab compared to -2.22 for adalimumab,  $p < 0.0001$ ). The study also met clinically important secondary endpoints including improvements in signs and symptoms of RA as measured by patients achieving a 20% improvement in the American College of Rheumatology (ACR) criteria (72% for sarilumab vs. 58% for adalimumab,  $p < 0.01$ ). Additional positive secondary endpoints included ACR50 and ACR70 response, and improvement in physical function, as measured by the Health Assessment Questionnaire - Disability Index (HAQ-DI) as compared to adalimumab ( $p < 0.01$  for all of these measures). DAS28-ESR is a measure of disease activity in RA, which includes the evaluation of 28 joints in the body for tenderness and swelling, a general health assessment, and ESR, a laboratory measure for inflammation. The incidence of AEs (64% for both groups), serious AEs (5% for sarilumab vs. 7% for adalimumab), infections (29% for sarilumab vs. 28% for adalimumab), and serious infections (1% for both groups) were generally similar between groups. Neutropenia, which was not associated with infections, was more common with sarilumab (14% for sarilumab vs. 1% for adalimumab), as has been seen in previous studies with IL-6 inhibitors. Injection site erythema (8% sarilumab vs. 3% adalimumab) was also more common with sarilumab. In November 2016, detailed results of SARIL-RA-MONARCH study were presented during the American College of

Rheumatology (ACR) Annual Meeting.

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### 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. We reported results of this study at the pre-specified primary endpoint (week 16) during 2015.

Top-line 52-week data were presented at the American Academy of Ophthalmology conference in October 2016.

### Polyarticular-course Juvenile Idiopathic Arthritis (pcJIA)

Phase 2 pcJIA Study. A Phase 2 study of sarilumab in pcJIA was initiated in the third quarter of 2016 and is currently enrolling patients.

Dupixent (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 3 Program. The LIBERTY AD Phase 3 clinical program consisted of five trials of patients with moderate-to-severe atopic dermatitis at sites worldwide. Patients from the LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, and LIBERTY AD SOLO 2 studies were transitioned to either the LIBERTY CONTINUE or LIBERTY AD Open label Extension trials.

In 2014, the FDA granted Breakthrough Therapy designation to Dupixent 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. The FDA has accepted for priority review the BLA for Dupixent for the treatment of adult patients with inadequately controlled moderate-to-severe atopic dermatitis. The target date for an FDA decision on the BLA is March 29, 2017. An FDA pre-approval inspection for Dupixent at Sanofi's Le Trait fill-and-finish facility has been scheduled for the first quarter of 2017. In addition, in December 2016, the EMA accepted for review the MAA for Dupixent for the treatment of adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

In 2015, the United Kingdom (UK) Medicines & Healthcare products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) Designation to Dupixent 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 Dupixent in advance of formal regulatory approval.

In April 2016, we and Sanofi announced positive top-line data from the Phase 3 LIBERTY AD SOLO 1 and SOLO 2 studies. These studies met their primary endpoints, and treatment with Dupixent as monotherapy significantly improved measures of overall disease severity, skin clearing, itching, quality of life, and mental health. A total of 1,379 adult patients with moderate-to-severe atopic dermatitis were enrolled in the identically-designed SOLO 1 and SOLO 2 trials. Patients were enrolled if they were not adequately controlled with topical medications, or if topical treatment was not medically advisable. All patients were assessed via the 5-point Investigator's Global Assessment (IGA) scale, ranging from 0 (clear) to 4 (severe); entry criteria required a baseline score of 3 or 4. Patients were also assessed using the Eczema Area and Severity Index (EASI) and other measures. Patients were randomized into one of three treatment groups: Dupixent 300 mg subcutaneously once per week, Dupixent 300 mg subcutaneously every two weeks, or placebo for 16 weeks following an initial Dupixent loading dose of 600 mg subcutaneously, or placebo. Results at 16 weeks included the following:

- For SOLO 1 and SOLO 2, respectively, 37% and 36% of patients who received Dupixent 300 mg weekly, and 38% and 36% of patients who received Dupixent 300 mg every two weeks, achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 10% and 8.5% with placebo ( $p < 0.0001$ ). This was the primary endpoint of the study in the United States.

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For SOLO 1 and SOLO 2, respectively, the percent improvement in EASI from baseline was 72% and 69% in patients who received the 300 mg weekly dose, and 72% and 67% for patients who received Dupixent 300 mg every two weeks, compared to 38% and 31% for placebo ( $p < 0.0001$ ).

For SOLO 1 and SOLO 2, respectively, 52.5% and 48% of patients who received Dupixent 300 mg weekly, and 51% and 44% of patients who received Dupixent 300 mg every two weeks, achieved EASI-75 compared to 15% and 12% with placebo ( $p < 0.0001$ ). This was the key secondary endpoint in the United States and one of the primary endpoints in the EU.

For the 16-week treatment period, the overall rate of AEs (65%-73% Dupixent and 65%-72% placebo) was comparable between the Dupixent groups and the placebo groups. The proportion of patients who completed the treatment period was 88%-94% for Dupixent and 80.5%-82% for placebo. The rate of serious AEs was 1%-3% for Dupixent and 5%-6% for placebo. Serious and severe infections were also numerically higher in the placebo groups in both studies (0.5%-1% Dupixent and 2%-3% placebo). AEs that were noted to have a higher rate with Dupixent treatment across both studies included injection site reactions (10%-20% Dupixent and 7%-8% placebo) and conjunctivitis (7%-12% Dupixent and 2% placebo); approximately 26% of patients in both studies reported a history of allergic conjunctivitis at study entry. No patient discontinued therapy due to injection site reactions and only one patient discontinued therapy due to conjunctivitis. More detailed results from SOLO 1 and SOLO 2 were presented at the European Academy of Dermatology and Venereology (EADV) conference in October 2016.

In the first quarter of 2016, the Phase 3 LIBERTY AD CAFÉ study of Dupixent in severe atopic dermatitis was initiated. This placebo-controlled study will investigate two dose regimens of Dupixent (300 mg weekly and 300 mg every two weeks) with concomitant topical corticosteroids in adult patients with severe atopic dermatitis who are not adequately controlled with, or are intolerant to or ineligible for, oral cyclosporine A therapy. The primary endpoint of this study will be the proportion of patients with a 75% or greater improvement from baseline in their EASI score.

In June 2016, we and Sanofi announced positive data from the Phase 3 LIBERTY AD CHRONOS study. This study met its primary and secondary endpoints, and Dupixent with topical corticosteroids (TCS) significantly improved measures of overall disease severity at 16 and 52 weeks, when compared to placebo with TCS. The primary endpoint results at week 16 were the following:

39% of patients who received either Dupixent 300 mg weekly with TCS or Dupixent 300 mg every two weeks with TCS achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 12% of patients receiving placebo with TCS ( $p < 0.0001$ ).

64% of patients who received Dupixent 300 mg weekly with TCS, and 69% of patients who received Dupixent 300 mg every two weeks with TCS achieved EASI-75, a 75% reduction on an index measuring eczema severity, compared to 23% of patients receiving placebo with TCS ( $p < 0.0001$ ).

The secondary endpoint 52-week results were the following:

40% of patients who received Dupixent 300 mg weekly with TCS, and 36% of patients who received Dupixent 300 mg every two weeks with TCS achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 12.5% of patients receiving placebo with TCS ( $p < 0.0001$ ).

64% of patients who received 300 mg weekly with TCS, and 65% of patients who received 300 mg every two weeks with TCS achieved EASI-75, compared to 22% with placebo with TCS ( $p < 0.0001$ ).

Patients were less likely to discontinue therapy in the Dupixent with TCS groups compared to placebo with TCS group (15% in both Dupixent groups; 33% placebo).

The overall rate of AEs in the LIBERTY AD CHRONOS study was comparable between the Dupixent with TCS groups (83% for the weekly dose (qw) and 88% for the every two weeks (q2w) dosing group) and the placebo with TCS group (84%). The rate of serious AEs was comparable between the Dupixent with TCS groups (3% (qw) and 4% (q2w)) and placebo with TCS group (5%). Serious and/or severe infections were numerically higher in the placebo with TCS group (1% in both Dupixent groups and 2% placebo). Adverse events that were noted to have a higher rate with Dupixent included injection site reactions (20% (qw) and 16% (q2w) Dupixent; 9% placebo) and conjunctivitis (19% (qw) and 13% (q2w) Dupixent; 8% placebo); 22% of patients on placebo, and 23% (qw) and 28% (q2w) of patients on Dupixent reported a history of allergic conjunctivitis at study entry.

Phase 2 Study in Pediatric Patients. Based on the results of a Phase 2 pharmacokinetic and safety study in pediatric patients (6-17 years of age) with moderate-to-severe atopic dermatitis, two Phase 3 pediatric studies (6-11 years of age and 12-17 years of age) are expected to be initiated in the first half of 2017.

In October 2016, the FDA granted Breakthrough Therapy designation for dupilumab for the treatment of moderate to severe (12 to less than 18 years of age) and severe (6 months to less than 12 years of age) atopic dermatitis in pediatric patients who are not adequately controlled with, or who are intolerant to, topical medication.

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Asthma

Phase 3 Study. A Phase 3 trial, LIBERTY ASTHMA QUEST, in adult and adolescent patients with uncontrolled persistent asthma was fully enrolled in the third quarter of 2016. 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. LIBERTY ASTHMA QUEST is a global, placebo-controlled Phase 3 study that enrolled more than 1,900 patients with uncontrolled persistent asthma and is evaluating two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

Nasal Polyps

Phase 3 Study. A Phase 3 study, LIBERTY NP SINUS, in adult patients with bilateral nasal polyps on a background therapy with intranasal corticosteroids was initiated in the fourth quarter of 2016.

Eosinophilic Esophagitis

Phase 2 Study. A Phase 2 trial of dupilumab in eosinophilic esophagitis was initiated in 2015 and is ongoing. 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

A Phase 3 study of REGN2222 (NURSERY Pre-Term) was initiated in 2015 and is currently enrolling patients. In 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 and chronic low back pain

Overview

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.

The fasinumab program is expected to consist of approximately 10,000 patients treated with fasinumab.

Table of Contents**Osteoarthritis**

Phase 2/3 Study. In the second quarter of 2015, we initiated a Phase 2/3 clinical study (16-weeks) in patients with moderate-to-severe osteoarthritis pain of the hip or knee who have a history of inadequate pain relief or intolerance to current analgesic therapies. In May 2016, we announced positive top-line data from the study. At 16 weeks, patients treated with all four doses of fasinumab demonstrated a statistically significant improvement in pain relief, the primary endpoint of the study, as well as improvements in the secondary measure evaluating physical function. The U.S. study enrolled 421 adult patients with moderate-to-severe osteoarthritis of the hip or knee who had a history of inadequate pain relief or intolerance to acetaminophen, and at least one oral nonsteroidal anti-inflammatory drug (NSAID) and an opioid. Patients in the study were experiencing significant pain at baseline with an average pain score of 6.3 on a 10-point scale. Patients were evaluated for pain, stiffness, and physical function using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in addition to other measures. Patients were randomized to one of five treatment groups in a 1:1:1:1:1 fashion; fasinumab 1mg, 3mg, 6mg, 9mg, or placebo, all delivered subcutaneously every 4 weeks through week 12, with the primary efficacy measured at week 16. Following week 16, patients were studied for an additional 20 weeks off treatment. On the primary endpoint, fasinumab-treated patients reported less pain at 16 weeks when compared to placebo on the 10-point WOMAC subscale for pain (-3.03 to -3.65 fasinumab vs. -2.25 placebo; p=0.03 through p=0.0001). Overall incidence of AEs, including serious and severe events, was similar across the fasinumab groups and placebo. As expected with antibodies to NGF, there was an increase in certain neuro-musculoskeletal AEs in the fasinumab treatment groups (17% combined fasinumab; 6% placebo) including arthralgia, paraesthesia, hypoaesthesia, and peripheral edema.

In October 2016, we and Teva announced that at the 36-week analysis of the Phase 2/3 clinical study in patients with moderate-to-severe osteoarthritis pain of the hip or knee, the incidence of adjudicated arthropathies was found to be potentially dose-dependent, with a higher rate of patients experiencing arthropathies in the higher dose groups (12% (9mg), 7% (6mg), 5% (3mg), 2% (1mg), and 1% (placebo)). In the ongoing fasinumab osteoarthritis pivotal Phase 3 program (further described below), we and Teva are planning to advance only the lower doses from the Phase 2/3 study, subject to discussion with the FDA and other health authorities. Updated data from the osteoarthritis pain Phase 2/3 study will be presented at upcoming medical congresses.

Phase 3 Study. In the first quarter of 2016, the FDA confirmed that we may proceed with studies of longer than sixteen-week duration. A Phase 3 long-term safety study in patients with pain due to osteoarthritis of the knee or hip was initiated in the first quarter of 2016.

**Chronic Low Back Pain**

A Phase 2b study in chronic low back pain was initiated in the first quarter of 2016. In October 2016, the FDA placed the Phase 2b study in chronic low back pain on clinical hold and requested an amendment of the study protocol; this was based on the FDA's recommendation that patients with advanced osteoarthritis at baseline not receive higher doses of fasinumab. Following this development, we completed an unplanned interim review of results and stopped dosing in the study. The unplanned analysis showed clear evidence of efficacy with improvement in pain scores in all fasinumab groups compared to placebo at the 8- and 12-week time points (nominal p<0.01). Preliminary safety results are generally consistent with what has been previously reported with the class. The Phase 2b chronic low back pain study enrolled approximately 70% of the targeted 800 patients in four dose groups: placebo, 6mg subcutaneously monthly, 9mg subcutaneously monthly, and 9mg intravenously every two months. Patients will continue to be followed for up to 36 weeks.

We and Teva plan to design pivotal Phase 3 studies in chronic low back pain. The companies plan to submit a pivotal program plan for review with the FDA and other health authorities.

Updated data from the chronic lower back pain Phase 2b study will be presented at upcoming medical congresses.

**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 March 2016, the New England Journal of Medicine published a paper based on the work done at the Regeneron Genetics Center showing that inactivating mutations of the angiotensin-like 4 (Angptl-4) gene are associated with a

significantly reduced risk of coronary artery disease in humans. Angptl-3 and Angptl-4 are related genes that both regulate lipoprotein lipase.

In 2015, we and BARDA entered into an agreement to develop, test, and manufacture a monoclonal antibody therapy for the treatment of Ebola virus infection. Under the terms of the agreement, HHS will provide funding to support our preclinical development, antibody manufacturing, and for a Phase 1 study in healthy volunteers, and has the option to provide additional funding for further manufacturing and development studies. In addition, in 2016, we and BARDA of the HHS entered into an

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agreement whereby HHS will provide certain funding to manufacture and study two antibody therapies for the potential treatment of Middle East Respiratory Syndrome (MERS).

### 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<sup>®</sup>, VelociMab, and other related technologies. The VelocImmune mouse platform is utilized to produce fully human monoclonal antibodies.

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

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

Our VelociMouse technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our VelociMouse technology are suitable for direct phenotyping or other studies. We have also developed our VelociMab platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our VelocImmune human monoclonal antibodies. We have utilized our VelociSuite technologies to develop a class of potential drug candidates, known as bi-specific antibodies. In the area of immunotherapies in oncology, we are exploring the use of bi-specific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. Our first such bi-specific antibody, which entered into clinical development in 2014, targets CD20 and CD3.

**Regeneron Genetics Center.** In 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.

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

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addition, RGC has expanded on its foundational population-based collaboration with Geisinger with a growing number of other institutions worldwide.

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 is responsible for funding up to \$130.0 million of our antibody discovery activities in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the 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 the right to extend antibody development and preclinical activities relating to selected programs for up to an additional three years after 2017. Sanofi must identify any programs to be extended by June 30, 2017, and we and Sanofi must then agree on a plan and budget for the extended activities. During the extended period, we will use commercially reasonable efforts to develop such antibodies and conduct preclinical activities through IND preparation. After 2017, funding from Sanofi under the Antibody Discovery Agreement will cease to continue, except with regard to the programs for which Sanofi has exercised its extension right.

For each drug candidate identified through discovery research under the Antibody Discovery Agreement (including drug candidates developed during the extended period of up to an additional three years described above), 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. 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.

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, sarilumab, and dupilumab in the United States. We have not exercised our option to co-promote any of these antibodies 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 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.

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 (up to \$200.0 million for 2017). 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 IO Collaboration products to the extent they are sufficient for this purpose. 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).

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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 IO Collaboration profits to the extent they are sufficient for this purpose. 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. 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. 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.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). We have principal control over the development of REGN2810, and the parties share equally, on an ongoing basis, development expenses for REGN2810 up to a total of \$650.0 million. We will lead commercialization activities in the United States, 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.

**Collaborations with Bayer**

EYLEA outside the United States. Since October 2006, we and Bayer 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 collaborate on, and share the costs of, the development of EYLEA. Bayer 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.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer 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 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 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.

Ang2 antibody outside the United States. In March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. Nesvacumab/aflibercept, a combination product candidate comprised of an antibody to Ang2 co-formulated with aflibercept, is being developed under the agreement. In connection with the agreement, Bayer made a \$50.0 million non-refundable up-front payment to us and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. We are also entitled to receive up to an aggregate of \$80.0 million in development milestone payments from Bayer. Bayer will share profits and losses from sales outside the United States equally with

us, and is responsible for certain royalties payable to Sanofi on sales of the product outside of the United States. Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales.

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### 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 made additional payments of \$45.0 million and \$15.0 million to us. We are also entitled to receive up to an aggregate of \$155.0 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 \$200.0 million.

### Collaboration with Teva

Fasinumab. In September 2016, we entered into a collaboration agreement with Teva to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with MTPC (as described above). In connection with the agreement, Teva made a \$250.0 million non-refundable up-front payment in September 2016. We will lead global development activities, and the parties will share equally, on an ongoing basis, development costs under a global development plan. In addition, we are entitled to receive up to an aggregate of \$460.0 million in development milestones and up to an aggregate of \$1,890.0 million in contingent payments upon achievement of specified annual net sales amounts. We are responsible for the manufacture and supply of fasinumab globally.

Within the United States, we will lead commercialization activities, and the parties will share equally in any profits or losses in connection with commercialization of fasinumab. In the territory outside of the United States, Teva will lead commercialization activities and we will supply product to Teva at a tiered purchase price, which is calculated as a percentage of net sales of the product (subject to adjustment in certain circumstances).

### Collaboration with Intellia Therapeutics

In April 2016, we entered into a license and collaboration agreement with Intellia Therapeutics, Inc., to advance CRISPR/Cas gene-editing technology for in vivo therapeutic development. We will collaborate with Intellia to conduct research for the discovery, development, and commercialization of new therapies (Product Collaboration), in addition to the research and technology development of the CRISPR/Cas platform (Technology Collaboration). In connection with the execution of the agreement, we made a \$75.0 million up-front payment in April 2016. We are responsible for costs of developing and commercializing CRISPR/Cas products under the Product Collaboration agreement and are also obligated to pay potential development and sales milestones, and royalties on any future sales of such products resulting from the development and commercialization of CRISPR/Cas products. In addition, under the Technology Collaboration agreement, we are responsible for funding certain research and technology development costs.

Under the terms of the Product Collaboration agreement, the parties agreed to a target selection process, whereby we may obtain exclusive rights in up to 10 targets to be chosen by us during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Of these 10 total targets, we may select up to five non-liver targets, while the remaining targets will be focused in the liver. Additionally, we may replace a limited number of targets with substitute targets upon the payment of a replacement fee, in which case rights to the replaced target(s) will revert to Intellia.

The Technology Collaboration term and the period for selecting targets for inclusion under the Product Collaboration both end in 2022, provided that we may make a payment to extend the term for an additional two-year period. The Product Collaboration agreement will continue until the date when no royalty or other payment obligations are due, unless earlier terminated in accordance with the terms of the agreement.

Certain targets that either we or Intellia select pursuant to the target selection process may be subject to a co-development and co-commercialization arrangement at our option or Intellia's option, as applicable. Transthyretin amyloidosis (ATTR), the first target selected by us, will be subject to the co-development and co-commercialization

arrangement between the parties.

In May 2016, Intellia completed an initial public offering (IPO) of its common stock and thereby triggered our obligation to purchase up to \$50.0 million of Intellia common stock in a concurrent private placement. As part of the concurrent private placement, we purchased from Intellia at the closing of the IPO shares of Intellia common stock for an aggregate purchase price of \$50.0 million.

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### Collaboration with Adicet Bio

In July 2016, we entered into a license and collaboration agreement with Adicet Bio, Inc., a privately held company, to develop next-generation engineered immune-cell therapeutics with fully human chimeric antigen receptors (CARs) and T-cell receptors (TCRs) directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells. In connection with the execution of the agreement, we made a \$25.0 million up-front payment to Adicet, and are obligated to provide Adicet with research funding over the course of a five-year research term.

Under the terms of the agreement, the parties will collaborate to identify and validate targets and work together to develop a pipeline of engineered immune-cell therapeutics for selected targets. We have the option to obtain development and commercial rights for a certain number of the product candidates developed by the parties, subject to an option payment for each product candidate. If we exercise our option on a given product candidate, Adicet then will have an option to participate in the development and commercialization for such product. If Adicet doesn't exercise its option, Adicet will be entitled to royalties on any future sales of such products by us. In addition to developing CARs and TCRs for use in novel immune-cell therapies as part of the collaboration, we will have the right to use these CARs and TCRs in our other antibody programs outside of the collaboration.

We will also be entitled to royalties on any future sales of products developed and commercialized by Adicet under the agreement for all products for which we do not have development and commercial rights.

### Manufacturing

We currently manufacture bulk drug materials at our manufacturing facilities in Rensselaer, New York, which consists of approximately 564,000 square feet of owned research, manufacturing, office, and warehouse space. We currently have approximately 97,000 liters of cell culture capacity at these 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. We currently are in the process of validating the facility, as required by regulatory authorities, for the manufacture of bulk drug materials.

Certain raw materials or other products necessary for the manufacture and formulation of our products and 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 our products and 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 by the FDA and other regulatory agencies 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 directors, medical 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. We have over 450 field-based employees in the United States, including personnel that have been recently hired in preparation for the potential approval of sarilumab and Dupixent.

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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.

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. We had sales to three customers (Besse Medical, a subsidiary of AmerisourceBergen Corporation; McKesson Corporation; and Curascript SD Specialty Distribution, a subsidiary of Express Scripts) that each accounted for more than 10% of total gross product revenue for the year ended December 31, 2016. On a combined basis, our product sales to these customers accounted for approximately 99% of our gross product revenue for the year ended December 31, 2016. We are also a party to collaboration agreements with Bayer 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, 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 (including CRVO and BRVO), diabetic retinopathy in patients with DME, and mCNV	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
Brolucizumab (RTH258), 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.	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	—

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



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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
LY3015014	In development (Phase 2)	Eli Lilly	Antibody against PCSK9	—
Inclisiran (ALN-PCSSc)	In development (Phase 2)	Anylam 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)	—
ETC-1002 (bempedoic acid)	In development (Phase 3)	Esperion Therapeutics, Inc.	ACL-inhibitor (oral, small molecule)	—
Gemcabene	In development (Phase 2)	Gemphire Therapeutics Inc.	Cholesterol synthesis inhibitor (oral, small molecule)	—
AMG-899 (TA-8995)	In development (Phase 2)	Amgen	CETP Inhibitor (oral, small molecule)	—
MEDI4166	In development (Phase 1)	AstraZeneca	Anti-PCSK9 antibody fused to a GLP-1 peptide (injectable, biologic)	—

The table above is not exhaustive. For additional information regarding the substantial competition Praluent faces, see also 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 in Development. 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 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. (in collaboration with Vitaeris Inc.)	Clazakizumab	In development (Phase 2)	Antibody against IL-6
	Ablynx	ALX-0061	In development (Phase 2)	Antibody against IL-6R
	R-Pharm	Olokizumab	In development (Phase 2)	Antibody against IL-6
	Roche	SA 237	In development (Phase 1/Phase 3)	Antibody against IL-6R
	Bird Rock Bio, Inc.	Gerilimzumab	In development (Phase 2)	Antibody against IL-6
Dupilumab (Phase 2/Phase 3) Target: IL-4R	GlaxoSmithKline	Nucala® (mepolizumab)	Approved	Antibody against IL-5
	Teva	Cinqair® (reslizumab)	Approved	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
	Galderma S.A.	Nemolizumab	In development (Phase 2)	Antibody against IL-31R
	Amgen (in collaboration with AstraZeneca)	AMG-157	In development (Phase 2)	Antibody against TSLP
	AstraZeneca	MEDI9314	In development (Phase 1)	Antibody against IL-4R
	Fasimumab (Phase 2b/Phase 3) Target: NGF REGN2222 (Phase 3)	Pfizer/Eli Lilly	Tanezumab	In development (Phase 3)
AstraZeneca		Synagis® (palivizumab)	Approved	Antibody against RSV-F protein

Target: RSV-F  
protein

AstraZeneca (in  
collaboration with AIMM  
Therapeutics)

MEDI8897

In development  
(Phase 2b)

Antibody against RSV-F  
protein

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The table above is not exhaustive and is focused on antibody competitors. We are also aware of several companies developing or marketing small molecules that may compete with our antibody product candidates in various indications, if such product candidates obtain regulatory approval in those indications. For sarilumab, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz<sup>®</sup> (tofacitinib citrate) and Eli Lilly's baricitinib may pose a competitive threat in the rheumatoid arthritis indication if sarilumab is approved in such indication. For dupilumab, Pfizer's Eucrisa<sup>®</sup> (crisaborole) may be a competitor in the atopic dermatitis indication if dupilumab is approved in such indication.

For additional information regarding our antibody programs and the substantial competition they face, see Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Products - Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition."

**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. 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"; and Part I, Item 3. "Legal Proceedings"). 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.

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The following table describes our U.S. patents and European patents (EP) that we currently consider of primary importance to our marketed products, including the territory, patent number, general subject matter class, and expected expiration dates. The noted expiration dates include any patent term adjustments. Certain of these patents may also be entitled to term extensions. We continue to pursue additional patents and patent term extensions in the United States and other jurisdictions covering various aspects of our products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table below. One or more patents with the same or earlier expiry date may fall under the same "general subject matter class" for certain products and are not separately listed.

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Product	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
EYLEA	aflibercept	US	7,070,959	Composition of Matter	June 16, 2023*
		US	8,092,803	Formulation	June 21, 2027
		US	9,254,338	Methods of Treatment	May 22, 2032
		EP	1183353	Composition of Matter	May 23, 2025**
		EP	2364691	Formulation	July 14, 2027
		EP	1544299	Methods of Treatment	May 23, 2020
Praluent***	alirocumab	US	8,062,640	Composition of Matter	December 15, 2029
		US	8,795,669	Formulation	July 27, 2032
		US	8,357,371	Methods of Treatment	December 21, 2029

\* A patent term extension has been granted by the U.S. Patent and Trademark Office, extending the original patent term (May 23, 2020), insofar as it covers EYLEA, to June 16, 2023.

\*\* Supplementary protection certificates have been granted in 14 European countries, extending the original patent term (May 23, 2020) in those countries to May 23, 2025, and are pending in nine additional European countries.

\*\*\* See Part I, Item 3. "Legal Proceedings" for information regarding the patent infringement proceedings relating to Praluent, which may impact Praluent's commercial availability in the United States and other jurisdictions.

In addition, in the United States and certain other countries, our competitive position may be enhanced due to the availability of market exclusivity under relevant law (for additional information regarding market exclusivity, see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - Loss or limitation of patent rights, and new regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products"). The effect of expiration of a patent relating to a particular product also depends upon other factors, such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product, and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

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. Our obligation to pay royalties to Genentech pursuant to these agreements terminated on May 7, 2016, when the licenses granted to us thereunder became fully paid up and royalty free for the duration of the remaining term of the underlying patents.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process applications with respect to our inventions.

However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

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

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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"; and Part I, Item 3. "Legal Proceedings").

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 are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we or Bayer 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. Before approving a new drug or biologic product, the FDA also 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.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

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

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

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### Business Segments

We manage our business as one segment which includes all activities related to the discovery, development, and commercialization of medicines for the treatment of serious medical conditions. For financial information related to our one segment, see Part II, Item 6. "Selected Financial Data" and our Consolidated Financial Statements and related notes.

### Employees

As of December 31, 2016, we had approximately 5,400 full-time employees, of whom approximately 700 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 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, 2016 and 2015, EYLEA net sales in the United States represented 68% and 65% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer 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: 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;

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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 differentiate EYLEA from Lucentis and other competitive products, 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;

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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;

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

risks associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below.

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

We and Bayer are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we or Bayer 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 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 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. In addition, in March 2016, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services released a proposed rule regarding a new payment model for the reimbursement by Medicare of drugs administered in the physician office or hospital outpatient department settings. If approved, the proposed rule could potentially redistribute and reduce reimbursement currently available to physicians and hospitals that furnish such drugs, including EYLEA, and may also impact physician prescription practices. 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 is approved in one or more jurisdictions for the treatment of wet AMD, macular edema following RVO (including CRVO and BRVO), DME, diabetic retinopathy in patients with DME, and mCNV. Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Pfenex is developing PF582 (a Phase 1b/2a trial in patients with wet AMD has been completed), and Formycon (in collaboration with Bioeq) 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 for the treatment of macular edema following RVO and for the treatment of DME) and Alimera's Iluvien (approved by the FDA 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 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, Ang2). Genentech/Roche is developing a bi-specific antibody targeting both VEGF and Ang2 for wet AMD and DME (currently in Phase 2 trials for both indications). 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.

In addition, ophthalmologists are using 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

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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 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. We are aware of one published study claiming that ZALTRAP (ziv-aflibercept) may be safely administered to the eye.

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 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 (which is terminable by Bayer at any time upon six or twelve months' advance notice), we rely on Bayer for sales, marketing, and distribution of EYLEA in countries outside the United States. If we and Bayer 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 collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA, particularly outside the United States. For additional information regarding our collaboration with Bayer, see "Risks Related to Our Reliance on Third Parties - If our collaboration with Bayer for EYLEA is terminated, or Bayer 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 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'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, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. 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'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 or 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 differentiate Praluent from Amgen's Repatha and other competitive products; the outcome of the pending patent infringement proceedings initiated by Amgen against us and Sanofi (described further in Part I, Item 3. "Legal Proceedings" of this report), and other risks associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below;

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;

payer restrictions on eligible patient populations and the reimbursement process, both in the United States and abroad;

our and Sanofi's ability to maintain sales of Praluent in the face of competitive products, including Repatha, as well as product candidates currently in clinical development;

the results of post-approval studies of (i) 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 (ii) other PCSK9 inhibitors, including Repatha, that could 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 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, EU, and other countries. 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

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new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition" below.

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, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process, including by means of required prior authorizations and utilization management criteria. 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, the eligible insured patient population for Praluent is limited, or a key payer refuses to provide reimbursement for Praluent in a particular jurisdiction altogether, 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 approvals in jurisdictions including the U.S., the EU, and Japan 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 AstraZeneca and Eli Lilly, 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 oral products and vaccines. 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, which is being developed by Esperion; and gemcabene, which is being developed by Gemphire.

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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. We also rely on Sanofi for sales, marketing, and distribution of Praluent in countries outside the United States. If we or 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

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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 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. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for sarilumab, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi facility in Le Trait, France where sarilumab is filled and finished; satisfactory resolution of these deficiencies is required before the BLA can be approved. For additional information, see "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." Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

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

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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, 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, and clinical trials evaluating our product candidates failed to meet the relevant endpoints. For example, in September 2016, we reported that in the Phase 2 study evaluating aflibercept co-formulated with rinucumab, an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), in patients with wet AMD, the combination therapy did not demonstrate an improvement in best corrected visual acuity compared to intravitreal aflibercept injection monotherapy at 12 weeks. 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.

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We are studying our antibody candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

EYLEA is being studied in additional indications, 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, and our European Patent No. 2,264,163 is, 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 or inter partes reexamination under the America Invents Act of 2011 or ex parte reexamination. Post-grant 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, or any other of our technologies, 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 patents and other intellectual property. For example, we are currently party 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. In addition, we are currently party 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.

We are aware of additional patents and pending patent 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 patent applications owned by others that respectively claim antibodies to IL-6R and methods of treating conditions including rheumatoid arthritis and uveitis with such antibodies; and antibodies to IL-4R and methods of treating conditions including atopic dermatitis and asthma with such antibodies. In addition to Praluent, our late-stage antibody-based pipeline includes sarilumab, an antibody to IL-6R, intended for the treatment of rheumatoid arthritis and non-infectious uveitis; Dupixent (dupilumab), an antibody to IL-4R, intended for the treatment of atopic dermatitis, asthma, nasal polyps, and eosinophilic esophagitis; REGN2222, an antibody targeting RSV-F; and fasinumab, an antibody to NGF. With respect to Dupixent, we are aware of certain patents owned by Immunex Corporation, a wholly owned subsidiary of Amgen. These patents include U.S. Patent No. 8,679,487 and European Patent No. 2,292,665 (the '665 Patent) and are generally directed to antibodies that bind to IL-4R. On September 30, 2016, Sanofi initiated a revocation proceeding to invalidate the U.K. counterpart of the '665 Patent in the United Kingdom. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the currently pending European Patent Office opposition proceedings initiated by us and Sanofi in relation to the '665 Patent. The original patent term of the Immunex patents is set to expire in 2021.

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 lawsuits for patent infringement and assert that their patents are valid and cover our late-stage antibody product candidates, similar to the patent infringement proceedings initiated by Amgen referred to above. 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.

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

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

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

Under the federal PPACA, enacted in 2010, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. 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.

A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

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 any 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) our current marketed products, including EYLEA and Praluent, 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 our ability to manufacture our marketed products at additional facilities (such as the Limerick, Ireland facility) in the future, 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 or commercial 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. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for sarilumab, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi facility in Le Trait, France where sarilumab and dupilumab are filled and finished; satisfactory resolution of these

deficiencies is required before the BLA can be approved. While the FDA subsequently reclassified the Sanofi Le Trait fill-and-finish facility as "acceptable" based on review of responses to an FDA Form 483, as well as proposed corrective actions, there is no guarantee that Sanofi will be able to resolve those deficiencies timely or at all. 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 in Development"). For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody product candidate 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 (in collaboration with Vitaeris), Ablynx, and

R-Pharm, 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), AstraZeneca (antibodies against IL-4R, 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 and Teva's Cinqair, both of which are antibodies against IL-5, may also compete with dupilumab, if dupilumab is approved. For RSV, AstraZeneca commercializes an antibody against RSV-F protein, Synagis, and other antibodies are in clinical development,

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including by AstraZeneca (in collaboration with AIMM Therapeutics). We are also aware of several companies developing or marketing small molecules that may compete with our antibody product candidates in various indications, if such product candidates obtain regulatory approval in those indications. For sarilumab, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz and Eli Lilly's baricitinib may pose a competitive threat in the rheumatoid arthritis indication if sarilumab is approved in such indication. For dupilumab, Pfizer's Eucrisa may be a competitor in the atopic dermatitis indication if dupilumab is approved in such indication.

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 our FDA registration and our National Drug Code, maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and 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, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process (including by means of required prior authorizations and utilization management criteria). In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost-containment and other

measures that are likely to adversely affect the amount of reimbursement for our current and future products. The full effects of this legislation depend on a number of factors, many of which are beyond our control, including new regulations and guidance 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

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of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

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

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the year ended December 31, 2016, product sales to three customers accounted on a combined basis for 99% of our total gross product revenue. 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 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 CMS, the agency responsible for implementing these disclosure requirements. We will need to continue to dedicate significant resources to comply with these requirements and to be prepared to comply with additional reporting obligations outside of the United States that may apply in the future. 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 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;

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new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;

- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign 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.

The current U.S. administration and Congress could carry out significant changes in legislation, regulation, and government policy (including with respect to the possible repeal of all or portions of the PPACA, possible changes in the existing treaty and trade relationships with other countries, and tax reform), as evidenced by statements and recent actions of the current president. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our products 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.

For example, on June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, it is expected that the British government will begin negotiating the terms of the United Kingdom's future relationship with the EU. We do not know to what extent Brexit will impact the business and regulatory environment in the United Kingdom, the rest of the EU, or other countries.

Changes impacting our ability to conduct business in the United Kingdom or other EU countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

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 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

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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 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 certain 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) \$130.0 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 in 2017 and (ii) \$825.0 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 over the term of 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

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efforts outside the United 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 trevogrumab, and decided not to opt in to the evinacumab and other programs. In addition, after 2017, we will be required to fund our antibody discovery activities and the research and preclinical development activities of our drug candidates, as Sanofi's funding obligations under the Antibody Discovery Agreement will cease to continue except with regard to the programs for which Sanofi has exercised its extension right.

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 for EYLEA is terminated, or Bayer 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 to assist with the development, and particularly the commercialization outside the United States, of EYLEA. Under our agreement with them, Bayer 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 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 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'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 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 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 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

collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA, particularly outside the United States.

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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, 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.

### 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., our President and 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, internal and external 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, result in demands for ransom or other forms of blackmail, or 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.

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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's sales of EYLEA outside the United States, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources 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, including sarilumab and dupilumab, 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 a collaborator), and expenses for which we are responsible in accordance with the terms of our collaboration agreements.

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. For example, on December 30, 2016, we entered into a purchase agreement pursuant to which we have agreed to purchase our existing corporate headquarters and other rentable area consisting of approximately 150 acres of predominately office buildings and laboratory space located in the towns of Mount Pleasant and Greenburgh, NY for a gross purchase price of \$720.0 million, subject to certain customary adjustments. The closing of the purchase is anticipated in the first quarter of 2017. Our obligation to consummate the purchase is not subject to a financing condition. While we have engaged a financing provider to use its best efforts to arrange a financing in connection with the contemplated purchase, there is no guarantee that we will be able to obtain such financing on the agreed 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, 2016, we had \$535.2 million in cash and cash equivalents and \$1,367.7 million in marketable securities (including \$49.2 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-

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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;
- 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;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- 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 maintaining its percentage ownership of our Common Stock but has previously publicly disclosed that it may opportunistically increase its percentage 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

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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, 2016, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 52.0% 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, 2016. As of December 31, 2016, Sanofi beneficially owned 23,418,396 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 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, 2016, holders of Class A Stock held 15.5% 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, 2016:

our current executive officers and directors beneficially owned 10.8% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2016, and 22.0% 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, 2016; and

our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 52.0% 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, 2016. In addition, these five shareholders plus our Chief Executive Officer held approximately 57.2% 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, 2016.

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 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.

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In addition, upon Sanofi reaching 20% ownership of our 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 outstanding shares of Class A Stock and Common Stock (taken together) and (ii) 25% of our 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 an initial director designee. Following the election and subsequent resignation of the initial designee, in January 2017, the board of directors elected N. Anthony Coles, M.D. as a successor Sanofi designee. Dr. Coles has been elected as a Class II director with a term expiring at the 2017 annual shareholder meeting.

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, 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 shareholder meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;

- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder," a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management."

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our License and Collaboration Agreement with Sanofi relating to our Antibody Collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving

us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our 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 and our 2016 ANG2 license and collaboration agreement with Bayer, Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of our company or acquiring more than 20% of our outstanding Class A Stock and Common Stock (taken together). With respect to each of these agreements, 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 by a third party or a group of third parties

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(other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our 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 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; or (v) other specified events, such as a liquidation or dissolution of our company.

Further, pursuant to the 2016 collaboration agreement between us and Teva, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of our company or acquiring more than 5% of our 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) 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 acquisition by a third party or a group of third parties of more than 30% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (v) the date of any issuance of shares of capital stock by us that would result in another party having more than 10% of the voting power of our 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 Teva; or (vi) other specified events, such as a liquidation or dissolution of our company.

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 has in the past served, and a successor Sanofi designee currently serves, on our board of directors. 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. A summary of our significant owned and leased properties is provided below.

#### Tarrytown, New York

At our Tarrytown, New York location, we lease approximately 1,180,000 square feet of laboratory and office space. Additionally, in 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our Tarrytown, New York location; 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. In December 2016, we entered into an agreement with the landlord of our Tarrytown, New York laboratory and office space to purchase this property and other rentable area - refer to Item. 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Tarrytown, New York Leases".

#### Sleepy Hollow, New York

In November 2016, we acquired a 383,000 square foot office building in Sleepy Hollow, New York, which we intend to utilize as additional office space to support the growth of our existing Tarrytown facilities.

#### Rensselaer, New York

We own facilities in Rensselaer, New York totaling approximately 564,000 square feet of research, manufacturing, office, and warehouse space. We also lease approximately 75,000 square feet of additional laboratory and office

space. During 2016, we acquired approximately 120-acres of undeveloped land near our Rensselaer, New York location. We intend to develop this property in connection with expanding our existing manufacturing and warehouse space.

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### Troy, New York

Additionally, in June 2016, we acquired a 217,000 square foot office building in Troy, New York, which we intend to utilize as additional office space to support the growth of our existing Rensselaer facilities.

### 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. We currently are in the process of validating the facility, as required by regulatory authorities, for the manufacture of bulk drug materials.

### 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, '163 Patent, and '018 Patent

We are party 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). Each of these patents concerns genetically engineered 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 patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting the '287 Patent and '163 Patent. A trial to adjudicate the claims of infringement and counterclaims of 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. On April 27, 2016, the court granted permission for our appeal and Kymab's cross-appeal, and on May 18, 2016, Regeneron and Kymab filed their respective notices to appeal the court's decision on the '287 and '163 Patents. The hearing for the appeal and the cross-appeal is currently scheduled for October 2017.

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 (currently stayed by agreement of the parties) and the United States District Court for the Southern District of New York, respectively. On November 21, 2014, the United States District Court for the Southern District of New York issued its Opinion and Order on Claim Construction in the '018 Patent infringement litigation, in which it held the '018 Patent invalid. 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. Oral argument on the appeal is currently scheduled for February 13, 2017.

Our '287 Patent was also the subject of opposition proceedings in the European Patent Office (EPO) initiated by Kymab and Merus in June 2013, alleging lack of novelty, lack of inventive step, and insufficiency. On September 17, 2014, following an oral hearing held to evaluate the validity of the '287 Patent, the Opposition Division of the EPO revoked the '287 Patent in its entirety on the grounds of lack of inventive step. Following our appeal, on November 9, 2015, the Technical Board of Appeal of the EPO (TBA) reversed the decision of the Opposition Division and found the amended claims of the '287 Patent were valid. The TBA issued a final, written decision in this matter on March 10, 2016.



On July 8 and July 13, 2016, notices of opposition against the '163 Patent were filed in the EPO by Merus N.V. and Kymab and Novo Nordisk A/S, respectively. The notices assert, as applicable, lack of novelty, lack of inventive step, and insufficiency. Our response to the oppositions was filed on December 30, 2016.

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Proceedings Relating to Praluent (alirocumab) Injection

As described in greater detail below, we are currently a party to patent infringement actions initiated by Amgen Inc. against us and Sanofi (and/or our and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent, which we are jointly developing and commercializing with Sanofi.

In the United States, Amgen has asserted a number of U.S. patents, which were subsequently narrowed to U.S. Patent Nos. 8,829,165 (the '165 Patent) and 8,859,741 (the '741 Patent), and seeks a permanent injunction to prevent us and the Sanofi defendants from manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, Commercializing) Praluent. 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. A jury trial in this litigation was held in the United States District Court for the District of Delaware from March 8 to March 16, 2016. During the course of the trial, the court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of Regeneron and the Sanofi defendants that there was no willful infringement of the asserted patent claims by Regeneron or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On January 3, 2017, the court issued a final opinion and judgment, denying our and the Sanofi defendants' motions for new trial and judgment as a matter of law. The court also denied as moot Amgen's motion to strike our and the Sanofi defendants' request to obtain a judgment as a matter of law, which allows the U.S. Court of Appeals for the Federal Circuit to address our and the Sanofi defendants' patent invalidity arguments on appeal. On January 12, 2017, we and the Sanofi defendants filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. On January 18, 2017, the U.S. Court of Appeals for the Federal Circuit ordered an expedited briefing schedule of the appeal on the merits, pursuant to which the briefing is scheduled to be completed no later than March 31, 2017. On January 31, 2017, Amgen filed a motion with the United States District Court for the District of Delaware to amend the court's final judgment to include an award of supplemental damages (including interest) and enhancement of such damages following the resolution of the appeal.

On March 23 and March 24, 2016, the United States District Court for the District of Delaware held a permanent injunction hearing to determine whether Regeneron and the Sanofi defendants should be prohibited from Commercializing Praluent in the United States. On January 5, 2017, the court granted the permanent injunction but delayed its imposition for 30 days (subsequently extended to 45 days) from the date of grant (i.e., until February 21, 2017). On January 13, 2017, we and the Sanofi defendants filed an emergency motion for stay of the permanent injunction pending appeal with the U.S. Court of Appeals for the Federal Circuit; and, on February 8, 2017, the court granted the stay pending appeal.

On July 25, 2016, Amgen filed a lawsuit against us, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of Amgen's European Patent No. 2,215,124 (the '124 Patent), which pertains to PCSK9 monoclonal antibodies, by Praluent. The lawsuit also seeks a permanent injunction, damages, an accounting of profits, and costs and interest. On February 8, 2017, the court temporarily stayed this litigation on terms mutually agreed by the parties.

Also on July 25, 2016, Amgen filed a lawsuit for infringement of the '124 Patent against us, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf, Germany, seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages. Oral hearing on this infringement lawsuit is currently scheduled for October 19, 2017.

On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against us, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie. Amgen is seeking the prohibition of allegedly infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the

ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time.

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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, of U.S. Patent No. 7,923,221 (the '221 Patent) jointly owned by Genentech, Inc. and City of Hope relating to the production of recombinant antibodies by host cells. On the same day, we and Sanofi-Aventis 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 (the "'415 Patent" and, together, with the "221 Patent", the "Cabilly Patents") jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies by host cells. On August 18, 2016, we and Sanofi-Aventis entered into a License and Settlement Agreement with Genentech and City of Hope that resolved all outstanding issues concerning the Cabilly Patents in the above-referenced litigation and inter partes review proceeding, resulting in a joint stipulation of dismissal being entered in the court and the USPTO. Under the agreement, Regeneron has been granted a license to the Cabilly Patents to make, use, and sell Praluent and all other antibody products under development at the time of the settlement.

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. On March 2, 2016, the defendants filed a motion to dismiss the shareholder derivative complaint. On August 16, 2016, the court heard oral argument on defendants' motion to dismiss. Pursuant to our By-Laws and the New York Business Corporation Law, expenses in connection with the foregoing are being advanced by us for the individual defendants.

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 pending motion to dismiss the shareholder derivative complaint, as discussed above.

Department of Justice Investigation

In January 2017, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to our support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning our provision of financial assistance to patients with respect to products sold or developed by us (including EYLEA, Praluent, ARCALYST, and ZALTRAP); and certain other related documents and communications. We are cooperating with this investigation.

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
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

## 2016

First Quarter	\$532.91	\$348.96
Second Quarter	433.93	329.09
Third Quarter	443.99	348.43
Fourth Quarter	452.96	325.35

As of February 1, 2017, there were 196 shareholders of record of our Common Stock and 18 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, 2011 through December 31, 2016. The comparison assumes that \$100 was invested on December 31, 2011 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.

	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016
Regeneron	\$ 100.00	\$ 308.62	\$ 496.55	\$ 740.12	\$ 979.38	\$ 662.26
S&P 500	\$ 100.00	\$ 113.41	\$ 146.98	\$ 163.72	\$ 162.53	\$ 178.02
NQ US Pharma TR Index	\$ 100.00	\$ 114.32	\$ 155.11	\$ 188.95	\$ 199.22	\$ 197.05

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 2016, we settled the conversion of \$12.9 million principal amount of our 1.875% convertible senior notes through the payment of \$12.9 million in cash (equal to the principal amount of the converted Notes) and issuance of 121,058 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 121,048 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 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 in the fourth quarter of 2016.

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
10/1/2016-10/31/2016	184	\$371.33	—	—

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## Item 6. Selected Financial Data

The selected financial data set forth below for the years ended December 31, 2016, 2015, and 2014 and as of December 31, 2016 and 2015 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, 2013 and 2012 and as of December 31, 2014, 2013, and 2012 are derived from our audited financial statements not included in this report.

(In thousands, except per share data)	Year Ended December 31,				
	2016	2015	2014	2013	2012
<b>Statement of Operations Data:</b>					
<b>Revenues:</b>					
Net product sales	\$3,338,390	\$2,689,478	\$1,750,762	\$1,425,839	\$858,093
Sanofi and Bayer collaboration revenue	1,402,935	1,339,361	1,036,854	650,400	493,913
Other revenue	119,102	74,889	31,941	28,506	26,471
	4,860,427	4,103,728	2,819,557	2,104,745	1,378,477
<b>Expenses:</b>					
Research and development	2,052,295	1,620,577	1,271,353	859,947	625,554
Selling, general, and administrative	1,177,697	838,526	519,267	346,393	229,859
Cost of goods sold	194,624	241,702	129,030	118,048	83,927
Cost of collaboration and contract manufacturing	105,070	151,007	75,988	37,307	528
	3,529,686	2,851,812	1,995,638	1,361,695	939,868
Income from operations	1,330,741	1,251,916	823,919	743,050	438,609
Other income (expense), net	(926 )	(26,819 )	(62,684 )	(46,668 )	(43,292 )
Income before income taxes	1,329,815	1,225,097	761,235	696,382	395,317
Income tax (expense) benefit <sup>(1)</sup>	(434,293 )	(589,041 )	(423,109 )	(282,644 )	347,081
Net income	\$895,522	\$636,056	\$338,126	\$413,738	\$742,398
Net income per share - basic	\$8.55	\$6.17	\$3.36	\$4.23	\$7.84
Net income per share - diluted	\$7.70	\$5.52	\$2.98	\$3.72	\$6.69
	As of December 31,				
(In thousands)	2016	2015	2014	2013	2012
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, and marketable securities (current and non-current)	\$1,902,944	\$1,677,385	\$1,360,634	\$1,083,875	\$587,511
Total assets	6,973,466	5,609,132	3,837,672	2,950,130	2,091,723
Convertible senior notes (current and non-current)	—	10,802	146,773	320,315	296,518
Facility lease obligations (current and non-current)	353,852	364,708	312,291	185,197	160,810
Capital lease obligations <sup>(2)</sup> (current and non-current)	127,274	—	—	126	1,309
Stockholders' equity	4,449,245	3,654,837	2,550,251	1,964,716	1,256,618

<sup>(1)</sup> As a result of our 2016 adoption of Financial Accounting Standards Board (FASB) Accounting Standards Update 2016-09, Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting, income taxes for the year ended December 31, 2016 included excess tax benefits in connection with stock-based compensation (previously, excess tax benefits were recognized in additional paid-in capital). 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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(2) In December 2016, we entered into an agreement to purchase facilities in Tarrytown, New York. Certain of the premises subject to the Purchase Agreement were historically accounted for as operating leases, and the related leases were deemed to be modified, as we now have the option to purchase such facilities. Consequently, the leases for such premises were re-classified as capital leases upon execution of the Purchase Agreement. See Note 12a to our Consolidated Financial Statements.

ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF  
7. 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 rheumatoid arthritis, asthma, atopic dermatitis, pain, cancer, and infectious diseases.

As described in Part I, Item 1. "Business - General," and "Business - Marketed Products," we currently have five products that have received marketing approval: EYLEA (aflibercept) Injection, Praluent (alirocumab) Injection, ARCALYST (rilonacept) Injection for Subcutaneous Use, Kevzara (sarilumab) Solution for Subcutaneous Injection, and ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion. We also have 16 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 15 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 2016 and 2017 to date were, and plans for the remainder of 2017 are, as follows:

Trap-based Clinical Program:

2016 and 2017 Events to Date

EYLEA

Bayer received regulatory approval for EYLEA for various indications and continued to pursue regulatory applications for marketing approval in additional countries

Initiated Phase 3 study for the treatment of NPDR in patients without DME

Reported positive top-line results from Phase 3 study in Japan for the treatment of NVG

2017 Plans

Bayer to submit for additional regulatory approvals outside the United States for various indications

Regulatory agency decisions on applications outside the United States for various indications

Continue patient enrollment in Phase 3 study for the treatment of NPDR in patients without DME

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Antibody-based Clinical Programs:		2017 Plans
Praluent (PCSK9 Antibody)	2016 and 2017 Events to Date	
	Reported positive results from Phase 3 ODYSSEY ESCAPE trial	Complete ODYSSEY OUTCOMES study
	DMC of ODYSSEY OUTCOMES study completed the first interim analysis for futility and recommended the study to continue with no changes	Submit for additional regulatory approvals outside the United States
	Supplemental BLA for monthly dosing regimen accepted for review by the FDA	Regulatory agency and reimbursement authority decisions on applications outside the United States
	Regulatory application filed for monthly dosing regimen in the EU	FDA target action date of April 24, 2017 for monthly dosing regimen
	Japanese MHLW approved Praluent for the treatment of uncontrolled LDL cholesterol in certain adult patients	
	ODYSSEY study data presented at the AHA Scientific Sessions 2016	
	DMC of ODYSSEY OUTCOMES study completed the second interim analysis for futility and overwhelming efficacy and recommended the study continue as planned	
	European Commission approved 300mg every 4 week dosing regimen	
	Court issued a permanent injunction barring commercialization of Praluent in the United States beginning February 21, 2017. On February 8, 2017, an emergency motion to stay (suspend) the injunction pending appeal was granted	
FDA extended review period for the supplemental BLA for monthly dosing regimen		
Sarilumab (IL-6R Antibody)	Reported positive top-line results from Phase 3 SARIL-RA-MONARCH trial	Re-submission of the BLA contingent upon successful completion of FDA re-inspection of Le Trait facility
	Regulatory applications submitted in the EU, Japan, and other jurisdictions outside the United States	Assuming successful re-submission, FDA action expected in the second quarter of 2017
	Presented 52-week top-line data from Phase 2 SARIL-NIU-SATURN study at American Academy of Ophthalmology conference	Submit for additional regulatory approvals outside the United States
	FDA issued CRL regarding the BLA	Regulatory agency decisions on applications outside the United States
	Initiated Phase 2 study in pcJIA	
	Presented detailed results of SARIL-RA-MONARCH study at ACR Annual Meeting	
Health Canada approved Kevzara for the treatment of adult patients with RA		



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Antibody-based Clinical Programs (continued):

	2016 and 2017 Events to Date	2017 Plans
Dupilumab (IL-4R Antibody)	<p>Reported positive top-line results from Phase 3 LIBERTY AD SOLO 1 and SOLO 2 trials in atopic dermatitis</p> <p>Initiated and completed enrollment in Phase 3 LIBERTY AD CAFÉ study in atopic dermatitis</p> <p>Reported positive results from Phase 3 LIBERTY AD CHRONOS study in atopic dermatitis FDA accepted for priority review the BLA for atopic dermatitis LIBERTY AD SOLO 1 and SOLO 2 results presented at EADV conference and simultaneously published in the New England Journal of Medicine</p> <p>Completed patient enrollment in pivotal Phase 3 LIBERTY ASTHMA QUEST study</p> <p>FDA granted Breakthrough Therapy designation for the treatment of atopic dermatitis in pediatric patients EMA accepted for review the MAA for atopic dermatitis Initiated Phase 3 study in patients with nasal polyps Completed patient enrollment in Phase 2 study in EoE</p>	<p>FDA target action date of March 29, 2017 for atopic dermatitis Submit for additional regulatory approvals in atopic dermatitis outside the United States Report results from Phase 3 asthma study Submit sBLA for asthma in adults</p> <p>Report results from Phase 2 study in EoE</p> <p>Initiate Phase 3 studies in pediatric patients in atopic dermatitis and asthma Initiate Phase 2 study in food allergies</p>
REGN2222 (RSV-F Antibody)		<p>Complete patient enrollment in Phase 3 NURSERY Pre-Term study Report results from Phase 3 study Continue patient enrollment in Phase 3 long-term safety study in osteoarthritis Report additional data from Phase 2/3 study in patients with osteoarthritis pain Initiate additional Phase 3 study in patients with osteoarthritis pain Initiate Phase 3 study in chronic low back pain</p>
Fasinumab (NGF Antibody)	<p>Initiated Phase 3 long-term safety study in patients with osteoarthritis of knee or hip</p> <p>Initiated Phase 2b study in chronic low back pain</p> <p>Reported positive top-line results from Phase 2/3 study in patients with osteoarthritis pain</p> <p>Phase 2b study in chronic low back pain put on clinical hold by FDA Performed an unplanned interim review of Phase 2b study results in chronic low back pain</p>	
Evinacumab (Angptl-3 Antibody)	<p>FDA granted orphan-drug designation for treatment of HoFH</p>	<p>Report additional results from Phase 2 HoFH</p>

study

Completed Phase 1 study in patients with dyslipidemia  
Reported positive interim results from ongoing  
proof-of-concept study in patients with HoFH  
Completed patient enrollment in Phase 2 HoFH study

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## Antibody-based Clinical Programs (continued):

	2016 and 2017 Events to Date	2017 Plans
Rinucumab/aflibercept (PDGFR-beta Antibody co-formulated with aflibercept)	Completed patient enrollment in Phase 2 study and reported top-line results Discontinued clinical development program Initiated Phase 2 studies in wet AMD and DME	Report results from Phase 2 studies
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	Completed patient enrollment in Phase 2 RUBY study in DME Completed patient enrollment in Phase 2 ONYX study in wet AMD	
REGN2810 (PD-1 Antibody)	Continued patient enrollment in Phase 1 study  Initiated Phase 2 potentially pivotal study for the treatment of advanced cutaneous squamous cell carcinoma Presented positive Phase 1 results from a dose-ranging study in heavily-pretreated patients with solid tumor cancers	Continue patient enrollment in Phase 1 and Phase 2 studies  Initiate Phase 2 study in non-small cell lung cancer  Initiate Phase 2 study in basal cell carcinoma
Trevogrumab (GDF8 Antibody)	Initiated Phase 1 combination therapy study with REGN2477	Continue patient enrollment in Phase 1 study
REGN1908-1909 (Feld1 Antibody)	Completed initial proof-of-concept study	Continue early stage development
REGN1979 (CD20 and CD3 Antibody)	Continued patient enrollment in Phase 1 study  Initiated Phase 1 study in combination with REGN2810 for treatment of B-cell malignancies	Complete patient enrollment in Phase 1 study
REGN3470-3471-3479 (Antibody to Ebola virus)	Initiated Phase 1 study in healthy volunteers  FDA granted orphan drug designation for the treatment of Ebola virus infection Completed patient enrollment in Phase 1 study in healthy volunteers	Initiate additional healthy volunteer study
REGN2477 (Activin A Antibody)	Initiated Phase 1 combination therapy study with trevogrumab in healthy volunteers Completed patient enrollment in Phase 1 study in healthy volunteers FDA granted orphan drug designation for the treatment of FOP	Initiate Phase 2 study in FOP patients
REGN3500 (IL-33 Antibody)	Initiated Phase 1 study in healthy volunteers  Completed patient enrollment in Phase 1 study in healthy volunteers Initiated Phase 1 study in patients with mild asthma	Initiate Phase 2 study in patients

REGN3767 (LAG-3 Antibody)	Initiated Phase 1 study (administered alone or in combination with REGN2810) in advanced malignancies	Continue patient enrollment in Phase 1 study
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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 sarilumab and Dupixent, 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, 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 and other 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, 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
Provision related to current period sales	93.4	154.4	30.4	278.2
Credits/payments	(87.1 )	(173.3 )	(27.3 )	(287.7)
Balance as of December 31, 2016	\$ 12.7	\$ 29.5	\$ 3.6	\$45.8

**Collaboration Revenue**

We earn collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize our technology platforms. These arrangements may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. The terms of these agreements typically include that consideration be provided to us in the form of non-refundable up-front 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 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. Our collaborators provide us with estimated development expenses for the most recent fiscal quarter. Our collaborators' 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 on a prospective basis accordingly, as necessary.

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 on a prospective basis 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 2016, 2015, and 2014, cost of goods sold included inventory write-downs and reserves totaling \$14.0 million, \$10.6 million, and \$6.0 million, respectively.

Contingencies

We accrue, based on management's judgment, for an estimated loss when the potential loss from claims or legal proceedings is considered probable and the amount can be reasonably estimated. As additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, we reassess the potential liability related to pending claims and litigation, and may change our estimates.

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## Results of Operations

## Net Income

Net Income (In millions)	Year Ended December 31,		
	2016	2015	2014
Revenues	\$4,860.4	\$4,103.7	\$2,819.6
Operating expenses	(3,529.7 )	(2,851.8 )	(1,995.6 )
Other income (expense), net	(0.9 )	(26.8 )	(62.7 )
Income before income taxes	1,329.8	1,225.1	761.3
Income tax expense	(434.3 )	(589.0 )	(423.1 )
Net income	\$895.5	\$636.1	\$338.2

Net income per share - diluted \$7.70      \$5.52      \$2.98

## Revenues

Revenues (In millions)	Year Ended December 31,		
	2016	2015	2014
Net product sales	\$3,338.4	\$2,689.5	\$1,750.8
Collaboration revenue:			
Sanofi	658.7	758.9	541.3
Bayer	744.3	580.5	495.6
Total collaboration revenue	1,403.0	1,339.4	1,036.9
Other revenue	119.0	74.8	31.9
Total revenues	\$4,860.4	\$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 and macular edema following BRVO in 2014, and diabetic retinopathy in patients with DME in 2015. In 2016, EYLEA net product sales increased to \$3,323.1 million from \$2,676.0 million in 2015, and \$1,736.4 million in 2014 due to higher sales volume. In 2016, 2015, and 2014, we also recognized ARCALYST net product sales of \$15.3 million, \$13.5 million, and \$14.4 million, respectively.



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Sanofi Collaboration Revenue (In millions)	Year Ended December 31,		
	2016	2015	2014
Antibody:			
Reimbursement of Regeneron research and development expenses	\$564.9	\$735.4	\$547.8
Reimbursement of Regeneron commercialization-related expenses	322.1	157.4	19.5
Regeneron's share of losses in connection with commercialization of antibodies	(459.1 )	(240.0 )	(41.4 )
Other	12.3	10.2	10.2
Total Antibody	440.2	663.0	536.1
Immuno-oncology:			
Reimbursement of Regeneron research and development expenses	138.5	40.0	—
Other	80.0	40.0	—
Total Immuno-oncology	218.5	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	\$658.7	\$758.9	\$541.3

In 2016, Sanofi's reimbursement of our antibody research and development expenses consisted of \$130.0 million under our Antibody Discovery Agreement and \$434.9 million under our License and Collaboration Agreement, compared to \$145.0 million and \$590.4 million, respectively, in 2015, and \$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 \$130.0 million, \$145.0 million, and \$160.0 million in 2016, 2015, and 2014, respectively. The lower reimbursement of research and development costs under our License and Collaboration Agreement in 2016 compared to 2015 was primarily due to decreased collaboration development activities for Praluent, dupilumab, and REGN2222. In 2016, Sanofi no longer co-develops and reimburses us for development activities for REGN2222. 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, sarilumab, and, effective in the first quarter of 2016, dupilumab.

In 2014, we and Sanofi began sharing commercial expenses related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In addition, effective in the first quarter of 2016, we and Sanofi also began sharing pre-launch commercialization expenses related to dupilumab. As such, during the same periods in which we recorded reimbursements from Sanofi related to our commercialization expenses, we also recorded our share of losses in connection with the companies preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and dupilumab within Sanofi collaboration revenue. Our share of losses in connection with commercialization of antibodies increased in 2016 compared to 2015 due to higher commercialization expenses in connection with the ongoing launch of Praluent, and higher expenses in connection with preparing to commercialize sarilumab and dupilumab. Our share of losses in connection with commercialization of antibodies increased in 2015 compared to 2014 primarily in connection with launching Praluent in the United States. In 2016, net product sales of Praluent in the United States were \$94.4 million and net product sales of Praluent outside of the United States were \$21.9 million. In 2015, net product sales of Praluent in the United States were \$9.5 million and net product sales of Praluent outside of the United States were \$1.0 million.

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. In 2016, Sanofi's reimbursement of our immuno-oncology research and



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development expenses consisted of \$86.5 million under our IO Discovery Agreement and \$52.0 million under our IO License and Collaboration Agreement related to REGN2810, compared to \$29.2 million and \$10.8 million, respectively in 2015.

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, 2016, \$520.0 million of the up-front payments was deferred and will be recognized ratably as revenue in future periods.

In February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement. Under the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP. As a result, in the first quarter of 2015, we recognized \$14.9 million of collaboration revenue, which was previously recorded as deferred revenue under the original 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 no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as we had no further performance obligations.

## Bayer Collaboration Revenue

Bayer Collaboration Revenue (In millions)	Year Ended December 31,		
	2016	2015	2014
EYLEA:			
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$649.2	\$466.7	\$301.3
Sales milestones	—	15.0	105.0
Cost-sharing of Regeneron EYLEA development expenses	9.0	8.9	23.4
Other	52.6	69.4	52.4
Total EYLEA	710.8	560.0	482.1
PDGFR-beta antibody:			
Cost-sharing of rinucumab/aflibercept development expenses	10.3	10.1	2.9
Other	9.6	10.4	10.6
Total PDGFR-beta antibody	19.9	20.5	13.5
Ang2 antibody:			
Cost-sharing of nesvacumab/aflibercept development expenses	8.0	—	—
Other	5.6	—	—
Total Ang2 antibody	13.6	—	—
Total Bayer collaboration revenue	\$744.3	\$580.5	\$495.6

Bayer 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 and mCNV (in Japan) in 2014, and macular edema following BRVO in 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 (In millions)	Year Ended December 31,		
	2016	2015	2014
Net product sales outside the United States	\$1,872.3	\$1,413.3	\$1,038.5
Regeneron's share of collaboration profit from sales outside the United States	703.3	521.8	358.3
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(54.1 )	(55.1 )	(57.0 )
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$649.2	\$466.7	\$301.3



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Bayer records revenue from sales of EYLEA outside the United States. 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 for a portion of the agreed-upon development expenses previously incurred by Bayer.

In 2015, we earned our final \$15.0 million sales milestone from Bayer, upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding \$200.0 million over a twelve-month period. In 2014, we earned seven \$15.0 million sales milestones from Bayer 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 decreased in 2015 compared to 2014. In January 2014, Bayer 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 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 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, including reimbursements for producing EYLEA commercial supplies for Bayer. In addition, other EYLEA revenue in the first five months of 2016 and for the full year of 2015 and 2014 includes Bayer's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States; the obligation to pay Genentech royalties on such sales ended in May 2016. Other EYLEA revenue also includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer. Cost-sharing of REGN2176-3 development expenses with Bayer commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement. Under the agreement, we conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, and Bayer is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front payment and non-substantive milestones received in the first quarter of 2014. As described above under Item 1. "Business - Clinical Programs - Ophthalmologic Diseases - EYLEA - Ophthalmologic Diseases", we discontinued clinical development of REGN2176-3 in the first quarter of 2017.

As described above under "Collaboration Agreements - Collaborations with Bayer - Ang2 antibody outside the United States," in March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a \$50.0 million non-refundable up-front payment to us, which was recorded as deferred revenue and is being recognized as revenue over the related performance period. Bayer is also obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States.

Other Revenue

As described in the "Collaboration Agreements" section above, in September 2015, we entered into a fasinumab collaboration agreement with MTPC, and, in September 2016, we entered into a fasinumab collaboration agreement with Teva. In connection with our fasinumab collaborations with MTPC and Teva, we recognized \$14.4 million and \$37.9 million, respectively, of other revenue during 2016. Revenue recognized during 2015 in connection with our fasinumab collaboration with MTPC was not material.

Under the terms of the Amended ZALTRAP Agreement, 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. In connection with the February 2015 Amended ZALTRAP Agreement, in 2016 we recorded \$26.2 million of revenue primarily related to a percentage of net sales of ZALTRAP that Sanofi is obligated to pay us and manufacturing ZALTRAP commercial supplies for Sanofi. In 2015, we recorded

\$38.8 million of revenue in connection with the Amended ZALTRAP Agreement 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.

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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 each of 2016, 2015, and 2014, we recognized \$23.6 million of revenue related to this agreement. In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris (canakinumab). In 2016, 2015, and 2014, other revenue included \$11.3 million, \$8.9 million, and \$7.9 million, respectively, of royalties from Novartis.

**Expenses**

Total operating expenses increased to \$3,529.7 million in 2016, from \$2,851.8 million in 2015 and \$1,995.6 million in 2014. Our average headcount in 2016 increased to 4,927 from 3,713 in 2015 and 2,629 in 2014, principally in connection with expanding our research and development, manufacturing, and commercialization activities.

Operating expenses in 2016, 2015, and 2014, included a total of \$559.9 million, \$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 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 2015 and 2014 compared to prior years. As of December 31, 2016, unrecognized Non-cash Compensation Expense related to outstanding stock options was \$888.0 million and unvested restricted stock awards was \$26.0 million. We expect to recognize this Non-cash Compensation Expense related to stock options and restricted stock awards over weighted-average periods of 1.9 years and 1.2 years, respectively.

**Research and Development Expenses**

Research and development expenses increased to \$2,052.3 million in 2016, from \$1,620.6 million in 2015 and \$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,			Increase (Decrease)	
	2016	2015	2014	2016 vs. 2015	2015 vs. 2014
Payroll and benefits <sup>(1)</sup>	\$597.5	\$506.3	\$401.6	\$91.2	\$104.7
Clinical trial expenses	370.6	306.1	203.0	64.5	103.1
Clinical manufacturing costs <sup>(2)</sup>	539.2	431.8	284.8	107.4	147.0
Research, licensing, and other development costs	257.6	133.6	137.2	124.0	(3.6 )
Occupancy and other operating costs	176.4	136.4	116.5	40.0	19.9
Cost-sharing of Bayer and Sanofi development expenses <sup>(3)</sup>	111.0	106.4	128.3	4.6	(21.9 )
Total research and development expenses	\$2,052.3	\$1,620.6	\$1,271.4	\$431.7	\$349.2

<sup>(1)</sup> Includes Non-cash Compensation Expense of \$264.3 million in 2016, \$216.6 million in 2015, and \$157.1 million in 2014.

<sup>(2)</sup> 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 \$48.7 million in 2016, \$39.1 million in 2015, and \$27.2 million in 2014.

<sup>(3)</sup> Under our collaborations with Bayer and Sanofi, in periods when Bayer or Sanofi incurs certain development expenses, we also recognize, as research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased in 2016 compared to 2015 primarily due to the initiation of additional clinical studies of fasinumab and REGN2810, and continued enrollment in clinical studies of these two antibody product candidates, partly offset by lower costs in connection with our dupilumab clinical program as some later-stage studies were completed. Clinical trial expenses increased in 2015 compared to 2014 primarily due

to additional costs for clinical studies of dupilumab and fasinumab, partly offset by lower Praluent, EYLEA, and trevogrumab costs. Clinical manufacturing costs increased in 2016 compared to 2015

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primarily due to costs related to manufacturing additional drug supplies of dupilumab, fasinumab, and REGN2810, partly offset by lower costs related to manufacturing less clinical supplies of Praluent. Clinical manufacturing costs increased in 2015 compared to 2014 primarily due to additional costs related to manufacturing drug supplies of dupilumab and, to a lesser extent, other late-stage antibody product candidates. Research, licensing, and other development costs increased in 2016 compared to 2015 primarily due to the \$75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia, the \$25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet, and an increase in lab supplies in connection with early stage research activities. Research and other development costs decreased in 2015 compared to 2014 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. Cost-sharing of Bayer and Sanofi development expenses increased in 2016 compared to 2015 primarily due to our obligation to fund 20% of Sanofi's Phase 3 dupilumab development costs, which commenced during the first quarter of 2016, partly offset by lower development costs incurred by Sanofi and Bayer in connection with other shared programs. Cost-sharing of Bayer and Sanofi development expenses decreased in 2015 compared to 2014 primarily due to lower development costs incurred by Bayer in connection with EYLEA and Sanofi in connection with sarilumab.

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 and Sanofi, the portion of Bayer'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  (In millions)	Year Ended December 31,			Increase (Decrease)	
	2016	2015	2014	2016 vs. 2015	2015 vs. 2014
Praluent	\$ 154.1	\$ 231.0	\$ 316.4	\$(76.9 )	\$(85.4 )
Dupilumab	449.5	404.0	169.0	45.5	235.0
Sarilumab	59.5	84.6	86.1	(25.1 )	(1.5 )
Fasinumab	170.8	56.1	8.2	114.7	47.9
REGN2222	60.9	42.6	16.7	18.3	25.9
REGN2810	119.9	39.4	22.1	80.5	17.3
Other product candidates in clinical development	259.2	221.4	281.9	37.8	(60.5 )
Other research programs and unallocated costs <sup>(1)</sup>	778.4	541.5	371.0	236.9	170.5
Total research and development expenses	\$2,052.3	\$1,620.6	\$1,271.4	\$431.7	\$349.2

<sup>(1)</sup> For the year ended December 31, 2016, includes the \$75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia and the \$25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet.

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.

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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 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 \$1,177.7 million in 2016 from \$838.5 million in 2015 primarily due to (i) higher commercialization-related expenses associated with Praluent and higher commercialization-related expenses in connection with preparing to launch sarilumab and dupilumab, (ii) higher contributions to not-for-profit organizations, including donations to independent not-for-profit patient assistance organizations, (iii) higher headcount and headcount-related costs, and (iv) higher Non-cash Compensation Expense principally for the reason described under "Expenses" above. 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 \$231.2 million, \$193.0 million, and \$134.7 million of Non-cash Compensation Expense in 2016, 2015, and 2014, respectively.

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 decreased to \$194.6 million in 2016 from \$241.7 million in 2015. Cost of goods sold primarily consists of costs in connection with producing U.S. EYLEA commercial supplies, various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility, and royalties. Cost of goods sold decreased in 2016 compared to 2015 principally due to the fact that, effective May 2016, we are no longer obligated to pay royalties to Genentech based on U.S. sales of EYLEA. This decrease was partly offset by an increase in Limerick start-up costs and an increase in U.S. EYLEA net sales. Cost of goods sold increased to \$241.7 million in 2015 from \$129.0 million in 2014 principally due to the increase in U.S. EYLEA net sales, as well as an increase in Limerick start-up costs. In 2016, 2015, and 2014, cost of goods sold included inventory write-downs and reserves totaling \$14.0 million, \$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, decreased to \$105.1 million in 2016 from \$151.0 million in 2015. This decrease was primarily due to lower royalties since our obligation to pay Genentech based on sales of EYLEA outside the United States also ended in May 2016.

Cost of collaboration and contract manufacturing 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. 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, 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.

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## Other Income (Expense)

Total other expenses (net of other income) in 2016 decreased compared to 2015 primarily due to (i) recognition of a \$0.5 million and \$18.9 million loss in 2016 and 2015, respectively, in connection with Notes which were surrendered for conversion during the respective periods, (ii) a decrease in interest expense related to conversions of a substantial portion of the Notes in 2015, and (iii) an increase in investment income on our marketable securities, partly offset by a 2016 other-than-temporary impairment charge of \$9.8 million related to our investment in Adverum Biotechnologies, Inc. (formerly Avalanche Biotechnologies, Inc.) common shares. The common shares of Adverum were previously acquired in connection with our research collaboration and license agreement with Adverum.

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 2016, we recorded income tax expense of \$434.3 million, based on an effective tax rate of 32.7%. The 2016 effective tax rate was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for research activities, offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. As described in Note 1 and Note 16 of our Consolidated Financial Statements, during 2016 we adopted Accounting Standards Update 2016-09, which requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital).

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.

## Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	As of December 31,		Increase (Decrease)
	2016	2015	
<b>Financial assets:</b>			
Cash and cash equivalents	\$535.2	\$809.1	\$ (273.9 )
Marketable securities - current	503.5	236.1	267.4
Marketable securities - non-current	864.2	632.2	232.0
	\$1,902.9	\$1,677.4	\$ 225.5
<b>Borrowings:</b>			
Convertible senior notes	\$—	\$10.8	\$ (10.8 )
<b>Working capital:</b>			
Current assets	\$3,180.2	\$2,915.1	\$ 265.1
Current liabilities	1,241.5	811.2	430.3
	\$1,938.7	\$2,103.9	\$ (165.2 )

Additionally, as of December 31, 2016, we had borrowing availability of \$750.0 million under a revolving credit facility (see further description under "Credit Facility" below).

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Sources and Uses of Cash for the Years Ended December 31, 2016, 2015, and 2014

Cash Flows from Operating Activities

2016. Net cash provided by operating activities was \$1,473.4 million in 2016. Our net income in 2016 included Non-cash Compensation Expense of \$559.9 million. Deferred tax assets as of December 31, 2016 increased by \$360.1 million, compared to December 31, 2015, primarily due to an increase in share-based compensation, the tax basis of intangible assets, and deferred revenue.

Inventories as of December 31, 2016 increased by \$149.8 million, compared to December 31, 2015, primarily due to increased production of commercial supplies of our drug products and preparing for commercial production to commence at our Limerick, Ireland facility. Deferred revenue increased by \$244.3 million as of December 31, 2016, compared to December 31, 2015, primarily due to \$250.0 million and \$60.0 million of payments received during 2016 from Teva and Mitsubishi, respectively, in connection with the companies' respective fasinumab collaborations, and the \$50.0 million up-front payment from Bayer in connection with the companies' Ang2 collaboration, partly offset primarily by the amortization of these 2016 payments and past up-front payments from Sanofi. Accounts payable, accrued expenses, and other liabilities increased by \$254.0 million as of December 31, 2016, compared to December 31, 2015, primarily due to higher tax related liabilities.

2015. Net cash provided by operating activities was \$1,330.8 million in 2015. Our net income in 2015 included Non-cash Compensation Expense of \$459.0 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.

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 in 2014 included Non-cash Compensation Expense of \$321.8 million and 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, and trade accounts receivable increased by \$34.9 million, compared to end-of-year 2013, primarily due to higher amounts receivable from Bayer in connection with the commercialization of EYLEA outside of 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. 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.

Cash Flows from Investing Activities

Net cash used in investing activities was \$1,046.9 million, \$907.6 million, and \$420.8 million in 2016, 2015, and 2014, respectively. In 2016, 2015, and 2014, purchases of marketable securities exceeded sales or maturities by

\$535.0 million, \$229.7 million, and \$87.8 million, respectively. Capital expenditures were \$511.9 million, \$677.9 million, and \$333.0 million in 2016, 2015, and 2014, respectively. Capital expenditures in 2016 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility, renovations and additions to certain areas of our Rensselaer, New York manufacturing facilities, the purchase of office buildings near our Rensselaer manufacturing facilities and Tarrytown facilities, and purchases of equipment.



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We expect to incur capital expenditures of \$375 million to \$450 million in 2017 primarily in connection with continued renovations of our Limerick, Ireland facility, expanding our Tarrytown, New York facilities, and expanding and renovating a portion of our manufacturing facilities at our Rensselaer, New York facility.

### Cash Flows from Financing Activities

Net cash used in financing activities was \$700.4 million, \$262.8 million, and \$218.5 million in 2016, 2015, and 2014, respectively. In 2016, 2015, and 2014, \$12.9 million, \$166.5 million, and \$220.6 million principal amount of our Notes, respectively, that was previously surrendered for conversion was settled in cash. Also during 2016, 2015, and 2014, we paid an aggregate amount of \$643.4 million, \$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 \$126.7 million in 2016, compared to \$206.4 million in 2015 and \$126.0 million in 2014. In 2015 and 2014, cash flows from financing activities included \$405.3 million and \$439.3 million, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations. In 2016, we elected to adopt Accounting Standards Update 2016-09, Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting; consequently, we began to record excess tax benefits as an operating activity in the statement of cash flows.

### Convertible Senior Notes

In October 2011, we issued \$400.0 million aggregate principal amount of Notes in a private placement. The Notes paid interest semi-annually on April 1 and October 1, and any notes that were not converted earlier matured on October 1, 2016. The Notes were 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.

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 covered the number of shares of our Common Stock that initially underlie the Notes, and were intended to reduce the potential dilutive impact of the conversion feature of the Notes. The convertible note hedge also terminated upon the maturity date of the Notes. The warrants were to become exercisable at various dates during 2017; however, in the fourth quarter of 2016, we entered into agreements with warrant holders to cancel any remaining warrants held by the warrant holders and to terminate the respective warrant agreements. See Note 11 to our Consolidated Financial Statements.

### 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 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, 2016.

Effective December 30, 2016, the Credit Agreement has been amended in connection with our proposed acquisition of the Facility (as described under "Tarrytown, New York Leases" below) and the related lease financing contemplated by us to provide that such lease financing and certain other lease or similar arrangements shall not constitute "Indebtedness" or "Capital Lease Obligations" for purposes of the Credit Agreement, including for purposes of calculating our total leverage ratio thereunder.

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, 2016.

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### License and Settlement Agreements with Genentech

As described above under Item 1. "Business - Patents, Trademarks, and Trade Secrets", in 2011 and 2013 we entered into license and settlement agreements with Genentech. The agreements provided for us to make payments to Genentech based on U.S. sales of EYLEA, as well as EYLEA manufactured in the United States and sold outside the United States, through May 7, 2016. EYLEA is sold outside the United States by affiliates of Bayer under our license and collaboration agreement with Bayer. Under the terms of the Genentech agreements, we were obligated to make a \$60.0 million milestone payment and pay royalties of 4.75% on cumulative relevant sales of EYLEA between \$400.0 million and \$3.0 billion and 5.5% on cumulative relevant sales of EYLEA over \$3.0 billion. All payments to Genentech were made by Regeneron, and Bayer shared in all such payments based on the proportion of EYLEA sales outside the United States to worldwide EYLEA sales.

### Tarrytown, New York Leases

We currently lease approximately 1,180,000 square feet of laboratory and office space at facilities in Tarrytown, New York. Certain leased premises have historically been accounted for as operating leases. However, for certain other buildings that we lease (related to approximately 735,000 square feet), we are deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, we capitalized the landlord's costs of constructing these new facilities, offset by a corresponding facility lease obligation. In addition, we recognized, as additional facility lease obligation, reimbursements from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we received from our landlord are deemed to be a financing obligation. As of December 31, 2016 and 2015, the facility lease obligation balance related to these buildings was \$353.9 million and \$364.7 million, respectively.

On December 30, 2016, we entered into a Purchase Agreement with BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC (collectively, BMR), pursuant to which we have agreed to purchase BMR's Tarrytown, New York facilities (the Facility), which includes the 1,180,000 square feet of laboratory and office space described above, for a purchase price of \$720.0 million, subject to certain customary adjustments. We currently occupy a significant portion of the Facility, with the remaining rentable area, or approximately 300,000 square feet, under leases to third-party tenants. In accordance with the terms of the Purchase Agreement, we paid \$57.0 million toward the purchase price to BMR in December 2016. The closing of the Purchase Agreement is anticipated in the first quarter of 2017.

We intend to fund the acquisition contemplated by the Purchase Agreement with a new financing. Accordingly, we have entered into an engagement letter with Banc of America Leasing & Capital, LLC (BAL), pursuant to which BAL has been engaged to use its best efforts to arrange a \$720.0 million lease financing in connection with the acquisition contemplated by the Purchase Agreement. As part of the contemplated financing, we intend to assign some or all our rights under the Purchase Agreement (including the right to take title to the Facility) to an affiliate of BAL at the closing of the financing, as a result of which such affiliate will become the legal owner of the Facility (the Lessor). Upon assignment of our rights, we expect to be reimbursed by BAL or an affiliate of BAL for the \$57.0 million payment we made in December 2016. Immediately thereafter, we intend to lease the Facility from the Lessor for a term of five years. At the end of the lease term, we expect to have an option to extend the term of the lease (subject to the consent of the financing providers), purchase the Facility at a predetermined amount, or sell the Facility to a third party on behalf of the Lessor.

### Funding Requirements

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). 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, will enable us to meet our projected operating needs for the foreseeable future.

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The following table summarizes our contractual obligations as of December 31, 2016.

(In millions)	Total	Payments Due by Period			
		Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
Purchase and other obligations <sup>(1)</sup>	\$ 1,022.6	\$ 579.3	\$ 353.4	\$ 42.0	\$ 47.9
Facility lease obligations <sup>(2) (3)</sup>	448.5	32.1	67.1	70.4	278.9
Capital leases <sup>(2) (3)</sup>	71.0	8.7	18.1	19.1	25.1
Operating leases <sup>(3)</sup>	51.3	9.9	10.8	8.3	22.3
Total contractual obligations	\$ 1,593.4	\$ 630.0	\$ 449.4	\$ 139.8	\$ 374.2

Purchase and other obligations primarily relate to research and development commitments, including those related to clinical trials, funding in connection with our sponsorship of the Science Talent Search and other programs by <sup>(1)</sup> the Society for Science & the Public, and capital expenditures. 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.

Represents rent payments with respect to capital lease and facility lease obligations in connection with our property leases in Tarrytown, New York, as described under "Tarrytown, New York Leases" above and Note 12 to our <sup>(2)</sup> Consolidated Financial Statements. Amounts in the table above exclude (i) potential future rent payments with respect to the lease we anticipate entering into in 2017, and (ii) the potential purchase price we would be obligated to pay if the anticipated financing pursuant to the engagement letter with BAL is not obtained.

<sup>(3)</sup> Excludes future contingent costs for utilities, real estate taxes, and operating expenses.

Liabilities for unrecognized tax benefits, totaling \$117.2 million at December 31, 2016, 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 expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical programs). 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 within Item 1. "Business - Collaboration Agreements - Collaborations with Sanofi," pursuant to the Antibody Discovery Agreement, as amended, Sanofi is responsible for funding up to \$130.0 million of our antibody discovery activities in 2017. Unless Sanofi, at its option, elects to extend antibody development and preclinical activities relating to selected programs, any future funding after 2017 from Sanofi under the Antibody Discovery Agreement will cease to continue. Clinical trial costs are dependent, among other things, on the size and duration of trials (for example, we have several ongoing late-stage clinical trials which are large and for which we expect to incur significant costs), 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.

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, including sarilumab and dupilumab. 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 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.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will be substantial. In addition, as described above under Item 3. "Legal Proceedings - Proceedings Relating to Praluent (alirocumab) Injection," the United States District Court for the District of Delaware issued a permanent injunction, which was stayed (suspended) pending appeal. If the injunction is upheld on appeal, it would prohibit us and the Sanofi defendants from commercializing Praluent

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in the United States. If we and Sanofi are not able to commercialize Praluent in the United States, our consolidated financial position, results of operations, and cash flows may be materially impacted.

We enter into research collaboration and licensing agreements that may require us to pay (i) amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant, and/or (ii) royalties calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted. Because of these factors, such payments are not included in the table of contractual obligations above. See Note 3 and Note 12 to our Consolidated Financial Statements.

Under our Antibody and IO Collaborations with Sanofi and our collaboration with Bayer 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 for a defined percentage (generally 50%) of agreed-upon development expenses funded by Sanofi and Bayer. 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, 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, 2016, our contingent reimbursement obligation to Bayer for EYLEA was approximately \$256 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration and IO Collaboration was approximately \$2,245 million and \$3 million, respectively. 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, if approved, sarilumab, dupilumab, and other product candidates developed as part of the Sanofi Antibody and IO Collaborations will be used to reimburse our collaborator for these obligations.

**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**

See Note 1 to our Consolidated Financial Statements for a summary of recently issued accounting standards.

**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 \$20.9 million and \$11.7 million decrease in the fair value of our investment portfolio as of December 31, 2016 and 2015, 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 2016, we recorded an other-than-temporary impairment charge of \$9.8 million related to our investment in an equity security (refer to Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Other Income (Expense)" above for further details). In 2015 and 2014, we recorded no charges for other-than-temporary impairments of our marketable securities.

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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 2016, 2015, and 2014, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. As of December 31, 2016, three customers accounted on a combined basis for 99% of our net trade accounts receivables. As of December 31, 2015, two customers accounted on a combined basis for 94% of our net trade accounts receivables.

### Foreign Exchange Risk

As discussed further above, Bayer 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-50 of this report. The supplementary financial information required by this Item is included at page F-50 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, 2016 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, 2016. The effectiveness of our internal control over financial reporting as of December 31, 2016 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, 2016 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 2017 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 2017 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 2017 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 2017 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 2017 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	Amended and Restated By-Laws. (Incorporated by reference from the Form 8-K for the Registrant filed December 21, 2016).
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 +	

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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.)

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- 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.)
- 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.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of
- 10.2.1 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.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of incentive
- 10.2.2 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.)  
Form of restricted stock award agreement and related notice of grant for use in connection with the grant of
- 10.2.3 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.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of
- 10.2.4 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.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of
- 10.2.5 non-qualified stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014  
+ Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year  
ended December 31, 2015, filed February 11, 2016.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of incentive
- 10.2.6 stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive  
+ Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31,  
2015, filed February 11, 2016.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of
- 10.2.7 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.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of incentive
- 10.2.8 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.)  
Form of restricted stock award agreement and related notice of grant for use in connection with the grant of
- 10.2.9 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.)  
Form of stock option agreement and related notice of grant for use in connection with the grant of
- 10.2.10 non-qualified stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals,  
+ Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the  
Registrant, for the year ended December 31, 2015, filed February 11, 2016.)  
Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and
- 10.3 + 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\* +

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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\* 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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10.9*	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.)
10.9.1*	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.)
10.10	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.)
10.11	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.)
10.11.1*	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.)
10.11.2	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.)
10.11.3	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.)
10.11.4	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.)
10.11.5	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.)
10.11.6	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.)
10.11.7	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.)
10.11.8	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.)
10.11.9	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.)
10.11.10	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.)
10.11.11	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.)
10.11.12	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.)
10.11.13	

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.)

10.11.14 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.)

10.11.15 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.)

10.11.16 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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- Seventeenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, 10.11.17 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.)
- Mt. Pleasant Lease by and between BMR-Landmark at Eastview LLC and the Registrant, dated April 3, 10.12 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
- First Amendment to Mt. Pleasant Lease, by and between BMR-Landmark at Eastview LLC and the 10.12.1 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.)
- Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between 10.13\* 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.)
- Amendment to the Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 by 10.13.1\* 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.)
- Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, 10.14\* 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.)
- Amendment No. 1 to Amended and Restated Discovery and Preclinical Development Agreement, dated July 10.14.1\* 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.)
- Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and 10.15\* 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.)
- First Amendment to Amended and Restated License and Collaboration Agreement by and between the 10.15.1\* 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.)
- Amendment No. 2 to Amended and Restated License and Collaboration Agreement, dated July 27, 2015 and 10.15.2\* 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.)
- Amended and Restated Investor Agreement, dated as of January 11, 2014, by and among Sanofi, 10.16 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.)
- Purchase Agreement, dated as of October 18, 2011, between the Registrant and Goldman, Sachs & Co. 10.17 (Incorporated by reference from the Form 8-K for the Registrant filed October 24, 2011.)
- Master Terms and Conditions for Convertible Note Hedging Transactions, dated as of October 18, 2011, as 10.18 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.)
- Master Terms and Conditions for Base Warrants, dated as of October 18, 2011, as supplemented by a 10.19 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.)
- Amendment, dated as of May 15, 2014, to the Master Terms and Conditions for Warrants, between Goldman, 10.20.1 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.)
- Second Amendment, dated as of November 25, 2014, to the Master Terms and Conditions for Warrants, 10.20.2 between Goldman, Sachs & Co. and the Registrant. (Incorporated by reference from the Form 10-K for the

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Registrant, for the year ended December 31, 2014, filed February 12, 2015.)

10.20.3 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.)

10.20.4 Termination Agreement, dated as of November 23, 2016, between Goldman, Sachs & Co. and the Registrant.

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- 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 Citibank, N.A. 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 Citibank, N.A. 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 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.)
- 10.22.2 Second Amendment, dated as of February 22, 2016, 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 March 31, 2016, filed May 5, 2016.)
- 10.22.3 Third Amendment, dated as of November 10, 2016, to the Master Terms and Conditions for Warrants, between Citibank, N.A. and the Registrant.
- 10.22.4 Termination Agreement, dated as of November 14, 2016, between Citibank, N.A. and the Registrant.
- 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 Credit Suisse International 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 Credit Suisse International 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 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.)
- 10.24.2 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.)
- 10.24.3 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.)
- 10.24.4 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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2015, filed February 11, 2016.)
- 10.24.5 Termination Agreement, dated as of November 15, 2016, between Credit Suisse Capital LLC (as assignee of Credit Suisse International) and the Registrant.
- 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 Morgan Stanley & Co. International plc 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 Morgan Stanley & Co. International plc 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 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.)
- 10.26.2 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.)

10.26.3 Termination Agreement, dated as of November 21, 2016, between Morgan Stanley & Co. International plc and the Registrant.

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10.27*	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.)
10.27.1*	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.)
10.27.2*	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.)
10.27.3	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.)
10.28*	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.)
10.29	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.)
10.29.1	Consent and Amendment No. 1 Memorandum, dated as of February 2, 2017, by and among the Registrant, as a borrower and guarantor; Regeneron Healthcare Solutions, Inc., Regeneron Genetics Center LLC, Regeneron International Unlimited Company, Regeneron Ireland Holdings Unlimited Company, Regeneron Ireland Unlimited Company, and Regeneron Capital International B.V., as subsidiary borrowers; JPMorgan Chase Bank, N.A., as administrative agent; and the lenders party thereto. (Incorporated by reference from the Form 8-K for the Registrant, filed February 7, 2017.)
10.30*	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.)
10.31*	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.)
10.32*	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.)
10.33*	ANG2 License and Collaboration Agreement, dated as of March 23, 2016, 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, 2016, filed May 5, 2016.)
10.34*	Collaboration Agreement, dated as of September 17, 2016, by and between Teva Pharmaceuticals International GmbH and Regeneron Ireland. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2016, filed November 4, 2016.)
10.35*	

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Purchase Agreement, dated as of December 30, 2016, by and among BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC and the Registrant.

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.

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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.

Item 16. Form 10-K Summary

None.

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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 9, 2017 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 9, 2017
/s/ ROBERT E. LANDRY Robert E. Landry	Senior Vice President, Finance and Chief Financial Officer (Principal Financial Officer)	February 9, 2017
/s/ DOUGLAS S. McCORKLE Douglas S. McCorkle	Vice President, Controller, and Assistant Treasurer (Principal Accounting Officer)	February 9, 2017
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	President, Chief Scientific Officer, and Director	February 9, 2017
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	Chairman of the Board	February 9, 2017
/s/ N. ANTHONY COLES N. Anthony Coles, M.D.	Director	February 9, 2017
/s/ CHARLES A. BAKER Charles A. Baker	Director	February 9, 2017
/s/ BONNIE L. BASSLER Bonnie L. Bassler, Ph.D.	Director	February 9, 2017
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	Director	February 9, 2017
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	Director	February 9, 2017
/s/ CHRISTINE A. POON Christine A. Poon	Director	February 9, 2017

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/s/ ARTHUR F. RYAN	Director	February 9, 2017
Arthur F. Ryan		
/s/ GEORGE L. SING	Director	February 9, 2017
George L. Sing		
/s/ MARC TESSIER-LAVIGNE	Director	February 9, 2017
Marc Tessier-Lavigne, Ph.D.		
/s/ HUDA Y. ZOGHBI	Director	February 9, 2017
Huda Y. Zoghbi, M.D.		

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<u>Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2016, 2015, and 2014</u>	<u>F- 4</u>
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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, 2016 and December 31, 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 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, 2016, 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 January 1, 2016, the Company prospectively changed the presentation of excess tax benefits and tax deficiencies in connection with stock-based compensation.

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 9, 2017



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## REGENERON PHARMACEUTICALS, INC.

## CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31,	
	2016	2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$535,203	\$809,102
Marketable securities	503,481	236,121
Accounts receivable - trade, net	1,343,368	1,152,489
Accounts receivable from Sanofi	92,989	153,152
Accounts receivable from Bayer	175,263	162,152
Inventories	399,356	238,578
Prepaid expenses and other current assets	130,528	163,501
Total current assets	3,180,188	2,915,095
Marketable securities	864,260	632,162
Property, plant, and equipment, net	2,083,421	1,594,120
Deferred tax assets	825,303	461,945
Other assets	20,294	5,810
Total assets	\$6,973,466	\$5,609,132
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$879,096	\$644,112
Capital lease obligations	127,274	—
Deferred revenue from Sanofi, current portion	115,267	101,573
Deferred revenue - other, current portion	116,397	51,914
Other current liabilities	3,461	13,563
Total current liabilities	1,241,495	811,162
Deferred revenue from Sanofi	503,474	582,664
Deferred revenue - other	327,298	82,015
Facility lease obligations	351,569	362,919
Other long-term liabilities	100,385	115,535
Total liabilities	2,524,221	1,954,295
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 - 1,911,456 in 2016 and 1,913,776 in 2015	2	2
Common Stock, \$.001 par value; 320,000,000 shares authorized; shares issued - 107,860,567 in 2016 and 106,378,001 in 2015	108	106
Additional paid-in capital	3,029,993	3,099,526
Retained earnings	1,748,222	852,700
Accumulated other comprehensive (loss) income	(12,840	) 8,572

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Treasury Stock, at cost; 3,763,868 shares in 2016 and 3,642,820 in 2015	(316,240 )	(306,069 )
Total stockholders' equity	4,449,245	3,654,837
Total liabilities and stockholders' equity	\$6,973,466	\$5,609,132

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,		
	2016	2015	2014
Statements of Operations			
Revenues:			
Net product sales	\$3,338,390	\$2,689,478	\$1,750,762
Sanofi collaboration revenue	658,665	758,873	541,299
Bayer collaboration revenue	744,270	580,488	495,555
Other revenue	119,102	74,889	31,941
	4,860,427	4,103,728	2,819,557
Expenses:			
Research and development	2,052,295	1,620,577	1,271,353
Selling, general, and administrative	1,177,697	838,526	519,267
Cost of goods sold	194,624	241,702	129,030
Cost of collaboration and contract manufacturing	105,070	151,007	75,988
	3,529,686	2,851,812	1,995,638
Income from operations	1,330,741	1,251,916	823,919
Other income (expense):			
Other income (expense), net	6,269	(12,578)	(25,312)
Interest expense	(7,195)	(14,241)	(37,372)
	(926)	(26,819)	(62,684)
Income before income taxes	1,329,815	1,225,097	761,235
Income tax expense	(434,293)	(589,041)	(423,109)
Net income	\$895,522	\$636,056	\$338,126
Net income per share - basic	\$8.55	\$6.17	\$3.36
Net income per share - diluted	\$7.70	\$5.52	\$2.98
Weighted average shares outstanding - basic	104,719	103,061	100,612
Weighted average shares outstanding - diluted	116,367	115,230	113,413
Statements of Comprehensive Income			
Net income	\$895,522	\$636,056	\$338,126
Other comprehensive income (loss):			
Unrealized (loss) gain on marketable securities, net of tax	(21,412)	(43,679)	53,439
Comprehensive income	\$874,110	\$592,377	\$391,565

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, 2016, 2015, and 2014  
(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, 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	—	—	—	—	326,815	—	—	—	—	326,815

charges										
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)

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## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Treasury Stock (Shares)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
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 with Company 401(k) Savings Plan contribution	—	—	31	—	15,382	—	—	—	15,382
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
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	3,099,838	3,700	(3,643)	(306,869)	3,654,837
Issuance of Common Stock in connection with exercise of stock options	—	—	1,697	2	115,180	—	—	—	115,182
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(382 )	—	143,182	—	—	—	143,182
Issuance of Common Stock in connection with conversion of convertible senior notes	—	—	121	—	48,004	—	—	—	48,004
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution	—	—	27	—	16,561	—	—	—	16,561
Issuance of restricted Common Stock under Long-Term Incentive Plan	—	—	17	—	—	—	—	—	—
Conversion of Class A Stock to Common Stock	(2 )	—	2	—	—	—	—	—	—

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## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	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		
Stock-based compensation charges	—	—	—	—	574,887	—	—	—	—	574,887
Acquisition of Common Stock in connection with exercise of convertible note hedges	—	—	—	—	10,171	—	(121 )	(10,171 )	—	—
Reduction of warrants	—	—	—	—	(643,365 )	—	—	—	—	(643,365 )
Reduction of equity component of convertible senior notes	—	—	—	—	(47,789 )	—	—	—	—	(47,789 )
Net income	—	—	—	—	—	895,522	—	—	—	895,522
Other comprehensive loss, net of tax	—	—	—	—	—	—	—	—	(21,412 )	(21,412 )
Balance, December 31, 2016	1,911	\$ 2	107,860	\$ 108	\$3,029,993	\$ 1,748,222	(3,764)	\$(316,240)	\$(12,840 )	\$4,449,245

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,		
	2016	2015	2014
Cash flows from operating activities:			
Net income	\$895,522	\$636,056	\$338,126
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	104,745	74,909	52,686
Non-cash compensation expense	559,878	459,049	321,750
Other non-cash charges and expenses, net	45,139	52,562	77,571
Deferred taxes	(360,078 )	(121,623 )	(53,276 )
Changes in assets and liabilities:			
Increase in Sanofi, Bayer, and trade accounts receivable	(143,827 )	(491,421 )	(34,927 )
Increase in inventories	(149,776 )	(111,825 )	(56,947 )
Decrease (increase) in prepaid expenses and other assets	23,543	(79,476 )	(45,327 )
Increase (decrease) in deferred revenue	244,270	608,892	(8,403 )
Increase in accounts payable, accrued expenses, and other liabilities	253,980	303,657	161,182
Total adjustments	577,874	694,724	414,309
Net cash provided by operating activities	1,473,396	1,330,780	752,435
Cash flows from investing activities:			
Purchases of marketable securities	(809,419 )	(557,105 )	(564,188 )
Sales or maturities of marketable securities	274,456	327,437	476,417
Capital expenditures	(511,941 )	(677,933 )	(333,006 )
Net cash used in investing activities	(1,046,904 )	(907,601 )	(420,777 )
Cash flows from financing activities:			
(Payments) proceeds in connection with capital and facility lease obligations	(27,689 )	26,020	(1,095 )
Repayments of convertible senior notes	(12,894 )	(166,467 )	(220,639 )
Payments in connection with reduction of outstanding warrants	(643,365 )	(573,487 )	(294,552 )
Proceeds from issuance of Common Stock	126,739	206,358	126,045
Payments in connection with Common Stock tendered for employee tax obligations	(143,182 )	(160,537 )	(267,584 )
Excess tax benefit from stock-based compensation	—	405,317	439,278
Net cash used in financing activities	(700,391 )	(262,796 )	(218,547 )
Net (decrease) increase in cash and cash equivalents	(273,899 )	160,383	113,111
Cash and cash equivalents at beginning of period	809,102	648,719	535,608
Cash and cash equivalents at end of period	\$535,203	\$809,102	\$648,719
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	\$5,454	\$10,582	\$20,348
Cash paid for income taxes	\$481,360	\$276,092	\$59,847

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

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(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's products that have received marketing approval consist of the following:

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 the EU, Japan, and certain other countries outside the United States for the treatment of myopic choroidal neovascularization (mCNV) and in the United States for the treatment of diabetic retinopathy in patients with DME. The Company is collaborating with Bayer on the 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 low-density lipoprotein ("LDL") cholesterol. Praluent is also available in certain countries in Europe 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. In July 2016, the Japanese Ministry of Health, Labour and Welfare ("MHLW") granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. The Company is collaborating with Sanofi on the global development and commercialization of Praluent. See Note 17 for information regarding the patent infringement proceedings relating to Praluent, which may impact Praluent's commercial availability in the United States and other jurisdictions.

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.

Kevzara™ (sarilumab) Solution for Subcutaneous Injection. In January 2017, Health Canada approved Kevzara for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have an inadequate response to or intolerance to one or more biologic or non-biologic disease modifying anti-rheumatic drugs ("DMARDs"). This is the first approval of Kevzara worldwide.

ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, known in the scientific literature as VEGF Trap, which is available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan ("FOLFIRI"), of patients with metastatic colorectal cancer ("mCRC") that is resistant to or has progressed following an oxaliplatin-containing regimen. Pursuant to a 2015 amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"), Sanofi is solely responsible for the development and commercialization of ZALTRAP, and Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP.



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.

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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. 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; provisions for loss contingencies; deferred tax asset valuation allowances; and the assessment of uncertain tax positions.

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

Included in Sanofi collaboration revenue is the Company's share of profits or losses from commercialization of antibodies, which is provided by Sanofi, and includes an estimate of the Company's share of profits or losses for the most recent fiscal quarter.

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

These estimates for the most recent period are adjusted on a prospective basis, 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 Consolidated 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). Realized gains and losses on marketable securities are included as a component of other income (expense), net. 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. If a decline in the fair value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the cost basis of the security to its current fair value and recognizes a loss as a charge against income.

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	10-40 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 revenue consists 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 and other 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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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 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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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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, 2016, three individual customers accounted for 99% of the Company's net trade accounts receivable balances. As of December 31, 2015, two individual customers accounted for 94% 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, 2016 and 2015, there were no reserves against trade accounts receivable. In addition, during the years ended December 31, 2016, 2015, and 2014, the Company did not recognize any charges for write-offs of trade accounts receivable.

Recently Issued Accounting Standards

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. The Company does not expect the new standard to have a material impact on the recognition of revenue from product sales. However, the Company continues to evaluate the impact that this guidance will have on its financial statements in connection with collaboration and license agreements.

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. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The implementation of the amendments is expected to increase the volatility of an entity's net income; however, the Company is not currently able to estimate the impact of adopting these amendments, as the significance of the impact will depend on the Company's equity investment balance upon adoption.

In February 2016, the FASB issued Accounting Standards Update 2016-02, Leases. The new standard requires a lessee to recognize in its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company is evaluating the impact that this guidance will have on the Company's financial statements.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-09 ("ASU 2016-09"), Compensation - Stock Compensation, Improvements to Employee Share-Based Payment

Accounting, which the Company elected to early adopt during the second quarter of 2016. ASU 2016-09 requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital). This aspect of ASU 2016-09 was adopted prospectively, and accordingly, the Company recorded excess tax benefits of \$144.8 million within income tax expense for the year ended December 31, 2016. Included within income tax expense for the year ended December 31, 2016 is \$15.6 million of excess tax benefits, which was previously recorded to additional paid-in capital during the first quarter of 2016. The amendments also require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Furthermore, the amendments require that excess tax benefits be classified as an operating activity in the statement of cash flows

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

(such amounts were previously included as a financing activity in the statement of cash flows); the Company also adopted this provision of ASU 2016-09 prospectively.

## 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 and macular edema following BRVO in 2014, and diabetic retinopathy in patients with DME in 2015. EYLEA net product sales in the United States totaled \$3,323.1 million, \$2,676.0 million, and \$1,736.4 million for the years ended December 31, 2016, 2015, and 2014, respectively. ARCALYST net product sales totaled \$15.3 million, \$13.5 million, and \$14.4 million for the years ended December 31, 2016, 2015, and 2014, respectively.

The Company's product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the years ended December 31, 2016, 2015, and 2014. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Year Ended December 31,		
	2016	2015	2014
Besse Medical, a subsidiary of AmerisourceBergen Corporation	55 %	67 %	73 %
McKesson Corporation	28 %	26 %	20 %
Curascript SD Specialty Distribution, a subsidiary of Express Scripts	16 %	**	**

\*\* For the periods ending December 31, 2015 and 2014, sales to Curascript SD Specialty Distribution represented less than 10% of total gross product revenue.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks, 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, 2016, 2015, and 2014.

	Rebates & Chargebacks	Distribution- Related Fees	Other Sales- Related Deductions	Total
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
Provision related to current period sales	93,385	154,477	30,442	278,304
Credits/payments	(87,092 )	(173,325 )	(27,285 )	(287,702)
Balance as of December 31, 2016	\$ 12,712	\$ 29,465	\$ 3,674	\$45,851

## 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.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## a. Sanofi

Sanofi owned a total of 23,418,396 shares of the Company's Common Stock as of December 31, 2016, 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.

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

Sanofi Collaboration Revenue	Year Ended December 31,		
	2016	2015	2014
Antibody:			
Reimbursement of Regeneron research and development expenses	\$564,900	\$735,439	\$547,761
Reimbursement of Regeneron commercialization-related expenses	322,149	157,350	19,480
Regeneron's share of losses in connection with commercialization of antibodies	(459,058 )	(240,042 )	(41,378 )
Other	12,177	10,243	10,243
Total Antibody	440,168	662,990	536,106
Immuno-oncology:			
Reimbursement of Regeneron research and development expenses	138,497	39,961	—
Other	80,000	40,000	—
Total Immuno-oncology	218,497	79,961	—
ZALTRAP:			
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	—	(4,715 )
Reimbursement of Regeneron research and development expenses	—	686	4,806
Other	—	15,236	5,102
Total ZALTRAP	—	15,922	5,193
	\$658,665	\$758,873	\$541,299

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

	As of December	
	2016	2015
Antibody:		
Accounts receivable, net	\$47,268	\$126,687
Deferred revenue	98,741	84,237
Immuno-oncology:		
Accounts receivable, net	\$40,647	\$21,394
Deferred revenue	520,000	600,000

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 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 the right to extend antibody development and preclinical activities relating to selected programs for up to an additional three years after 2017. Sanofi must identify any programs to be extended by June 30, 2017, and the Company and Sanofi must then agree on a plan and budget for the extended activities. During the extended period, the Company will use commercially reasonable efforts to develop such antibodies and conduct preclinical activities through IND preparation. After 2017, funding from Sanofi under the Antibody Discovery Agreement will cease to continue, except with regard to the programs for which Sanofi has exercised its extension right.

For each drug candidate identified under the Antibody Discovery Agreement (including drug candidates developed during the extended period of up to an additional three years described above), 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 \$10.0 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.

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, the Company recognized as research and development expense \$108.6 million, \$92.6 million, and \$109.7 million in 2016, 2015, and 2014, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent, sarilumab, and, commencing in the first quarter of 2016, dupilumab. 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 \$2,245 million as of December 31, 2016.

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 equally share profits and losses from sales within the United States. The parties 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 \$250.0 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

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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. 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. 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.

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" in the table above represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and effective in the first quarter of 2016, dupilumab.

In 2014, the Company and Sanofi began sharing commercialization expenses related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In addition, effective in the first quarter of

2016, the Company and Sanofi also began sharing pre-launch commercialization expenses related to dupilumab. As such, during the same periods that the Company recorded reimbursements from Sanofi related to the Company's commercialization expenses, the Company also recorded its share of losses in connection with the companies preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and dupilumab within Sanofi collaboration revenue.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 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 (including a limit of \$150.0 million in 2016), 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 IO Collaboration 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. The Company's contingent reimbursement obligation to Sanofi under the IO Collaboration was approximately \$3 million as of December 31, 2016. 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 IO Collaboration 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 \$2.0 billion in any consecutive twelve-month period.

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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.

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 is being 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 for patients with 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 the 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 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. 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 years ended December 31, 2016 and 2015, the Company recorded \$26.2 million and \$38.8 million, respectively, in other revenue, primarily related to a percentage of net sales of ZALTRAP and manufacturing ZALTRAP commercial supplies for Sanofi.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## b. Bayer

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

	Year Ended December 31,		
	2016	2015	2014
Bayer Collaboration Revenue			
EYLEA:			
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	\$ 649,232	\$ 466,667	\$ 301,302
Sales milestones	—	15,000	105,000
Cost-sharing of Regeneron EYLEA development expenses	9,010	8,887	23,383
Other	52,527	69,466	52,390
Total EYLEA	710,769	560,020	482,075
PDGFR-beta antibody:			
Cost-sharing of rinucumab/aflibercept (REGN2176-3) development expenses	10,291	10,075	2,848
Other	9,576	10,393	10,632
Total PDGFR-beta antibody	19,867	20,468	13,480
Ang2 antibody:			
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	8,036	—	—
Other	5,598	—	—
Total Ang2 antibody	13,634	—	—
	\$ 744,270	\$ 580,488	\$ 495,555

Deferred revenue in connection with the Company's collaboration agreements with Bayer is as follows:

	As of December	
	31,	
	2016	2015
EYLEA	\$ 62,373	\$ 46,694
PDGFR-beta antibody	—	9,522
Ang2 antibody	45,739	—

## EYLEA outside the United States

In October 2006, the Company entered into a license and collaboration agreement with Bayer for the global development and commercialization outside the United States of EYLEA. Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of \$75.0 million. The Company also received from Bayer 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.

Since 2009, all agreed-upon EYLEA development expenses incurred by the Company and Bayer, 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 has the right to terminate the license and collaboration 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.

Bayer 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 and mCNV (in Japan) in 2014, and macular edema following BRVO in 2015.





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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Bayer 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, the Company is entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales. 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. The Company is obligated to reimburse Bayer 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 has incurred in accordance with a formula based on the amount of development expenses that Bayer 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 was approximately \$256 million as of December 31, 2016.

In 2014, the Company earned, and recorded as revenue, \$90.0 million of sales milestone payments from Bayer upon total aggregate net sales of EYLEA outside the United States achieving certain specified levels starting at \$500.0 million over a twelve-month period. In addition, in connection with a November 2013 agreement under which Bayer 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 upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding \$100.0 million over a twelve-month period. In 2015, the Company earned, and recorded as revenue, the final sales milestone payment from Bayer, in the amount of \$15.0 million, upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding \$200.0 million over a twelve-month period.

In January 2014, Bayer 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 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 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 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's EYLEA development expenses that the Company is obligated to reimburse. In 2016, 2015, and 2014, the Company recognized as research and development expense \$1.4 million, \$13.7 million, and \$18.6 million, respectively, of EYLEA development expenses that the Company was obligated to reimburse to Bayer.

**PDGFR-beta antibody outside the United States**

In January 2014, the Company entered into a license and collaboration agreement with Bayer governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), including REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept. The agreement provides that the Company would conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer would have a right to opt-in to license and collaborate on further development and commercialization outside the United States. Effective in the first quarter of 2017, the Company has discontinued clinical development of REGN2176-3.

In connection with the agreement, Bayer 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 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 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).

From inception of the agreement until Bayer 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 were also initially recorded as deferred revenue and will be recognized over the same performance period as the up-front payment.

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Ang2 antibody outside the United States

In March 2016, the Company entered into an agreement with Bayer governing the joint development and commercialization outside the United States of an antibody product candidate to angiopoietin-2 (Ang2), including in combination with aflibercept, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a \$50.0 million non-refundable up-front payment to the Company and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. The Company is also entitled to receive up to an aggregate of \$80.0 million in development milestone payments from Bayer. Bayer will share profits and losses from sales outside the United States equally with the Company, and is responsible for certain royalties payable to Sanofi on sales of the product outside of the United States. Within the United States, the Company has exclusive commercialization rights and will retain all of the profits from sales. At the inception of the agreement, the Company's significant deliverables consisted of (i) a 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, as such right was not sold separately by the Company, nor could Bayer 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 \$50.0 million up-front payment was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

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 an Ang2 antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both the Company and Bayer.

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 agreement, MTPC made a \$10.0 million non-refundable up-front payment. In the first quarter of 2016, MTPC made additional payments of \$45.0 million and \$15.0 million to the Company, which were recorded as deferred revenue and are being recognized ratably as revenue over the same performance period as the up-front payment. The Company is entitled to receive up to an aggregate of \$65.0 million in development milestones if achieved by the Company and \$90.0 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 \$200.0 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, the deliverables were considered a single unit of accounting. Consequently, the \$10.0 million up-front payment was initially recorded as deferred revenue, and is being recognized

ratably as revenue over the related performance period.

The Company recognized \$14.4 million of revenue in 2016 in connection with the MTPC Collaboration Agreement. Revenue recognized in connection with this agreement was not material in 2015.

d. Teva

In September 2016, the Company and Teva entered into a collaboration agreement (the "Teva Collaboration Agreement") to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to the Company's collaboration agreement with MTPC (as described above). In connection with the Teva Collaboration Agreement, Teva made a \$250.0 million non-refundable up-front payment in September 2016. The Company will lead global development activities, and the parties will

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

share equally, on an ongoing basis, development costs under a global development plan. In addition, the Company is entitled to receive up to an aggregate of \$460.0 million in development milestones and up to an aggregate of \$1,890.0 million in contingent payments upon achievement of specified annual net sales amounts. The Company is responsible for the manufacture and supply of fasinumab globally.

Within the United States, the Company will lead commercialization activities, and the parties will share equally in any profits and losses in connection with commercialization of fasinumab. In the territory outside the United States, Teva will lead commercialization activities and the Company will supply product to Teva at a tiered purchase price, which is calculated as a percentage of net sales of the product (subject to adjustment in certain circumstances). Unless terminated earlier in accordance with its provisions, the Teva Collaboration Agreement will continue to be in effect until such time as neither party is developing or commercializing fasinumab.

At the inception of the Teva Collaboration Agreement, the Company's significant deliverables consisted of (i) a 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 Teva receive any benefit from the license without the fulfillment of the other ongoing obligations by the Company, including the clinical supply arrangement. Therefore, the deliverables were considered a single unit of accounting. Consequently, the \$250.0 million up-front payment was initially recorded as deferred revenue, and is being recognized ratably as revenue over the related performance period.

The Company recognized \$37.9 million of revenue in 2016 in connection with the Teva Collaboration Agreement.

e. Intellia Therapeutics

In April 2016, the Company entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas gene-editing technology for in vivo therapeutic development. The Company will collaborate with Intellia to conduct research for the discovery, development, and commercialization of new therapies ("Product Collaboration"), in addition to the research and technology development of the CRISPR/Cas platform ("Technology Collaboration"). In connection with the execution of the agreement, the Company made a \$75.0 million up-front payment, which was recorded as research and development expense in the second quarter of 2016, and also agreed to purchase Intellia shares contingent upon Intellia consummating its next equity financing. The Company is responsible for costs of developing and commercializing CRISPR/Cas products under the Product Collaboration agreement and is also obligated to pay potential development and sales milestones, and royalties on any future sales of such products resulting from the development and commercialization of CRISPR/Cas products. In addition, under the Technology Collaboration agreement, the Company is responsible for funding certain research and technology development costs. Under the terms of the Product Collaboration agreement, the parties agreed to a target selection process, whereby the Company may obtain exclusive rights in up to 10 targets to be chosen by the Company during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Additionally, the Company may replace a limited number of targets with substitute targets upon the payment of a replacement fee, in which case rights to the replaced target(s) will revert to Intellia.

The Technology Collaboration term and the period for selecting targets for inclusion under the Product Collaboration both end in 2022, provided that the Company may make a payment to extend the term for an additional two-year period. The Product Collaboration agreement will continue until the date when no royalty or other payment obligations are due, unless earlier terminated in accordance with the terms of the agreement.

Certain targets that either the Company or Intellia select pursuant to the target selection process may be subject to a co-development and co-commercialization arrangement at the Company's option or Intellia's option, as applicable.

In May 2016, Intellia completed an initial public offering ("IPO") of its common stock and thereby triggered the Company's obligation to purchase up to \$50.0 million of Intellia common stock in a concurrent private placement. As part of the concurrent private placement, the Company purchased from Intellia at the closing of the IPO 2,777,777

shares of Intellia common stock for an aggregate purchase price of \$50.0 million (see Note 6).

f. Adicet Bio

In July 2016, the Company entered into a license and collaboration agreement with Adicet Bio, Inc., a privately held company, to develop next-generation engineered immune-cell therapeutics with fully human chimeric antigen receptors ("CARs") and T-cell receptors ("TCRs") directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

tumor cells. In connection with the execution of the agreement, the Company made a \$25.0 million up-front payment to Adicet, which was recorded as research and development expense in the third quarter of 2016, and is obligated to provide Adicet with research funding over the course of a five-year research term.

Under the terms of the agreement, the Company and Adicet will collaborate to identify and validate targets and work together to develop a pipeline of engineered immune-cell therapeutics for selected targets. The Company has the option to obtain development and commercial rights for a certain number of the product candidates developed by the parties, subject to an option payment for each product candidate. If the Company exercises its option on a given product candidate, Adicet then will have an option to participate in the development and commercialization for such product. If Adicet doesn't exercise its option, Adicet will be entitled to royalties on any future sales of such products by the Company. In addition to developing CARs and TCRs for use in novel immune-cell therapies as part of the collaboration, the Company will have the right to use these CARs and TCRs in its other antibody programs outside of the collaboration.

The Company will also be entitled to royalties on any future sales of products developed and commercialized by Adicet under the agreement for all products for which the Company does not have development and commercial rights.

g. 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 2010, which was deferred upon receipt and is being recognized as revenue ratably over a 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, 2016, 2015, and 2014, the Company recognized \$23.6 million of other revenue. In addition, deferred revenue at December 31, 2016 and 2015 in connection with the Astellas license agreement was \$33.9 million and \$57.4 million, respectively.

5. Marketable Securities

Marketable securities as of December 31, 2016 and 2015 consist of both debt securities of investment grade issuers as well as equity securities.





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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2016				
Corporate bonds	\$1,076,964	\$630	\$(4,743)	\$1,072,851
U.S. government and government agency obligations	132,923	58	(641)	132,340
Municipal bonds	7,663	1	(20)	7,644
Commercial paper	63,074	1	—	63,075
Certificates of deposit	42,612	—	—	42,612
Equity securities	57,251	5,551	(13,583)	49,219
	\$1,380,487	\$6,241	\$(18,987)	\$1,367,741
As of December 31, 2015				
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	14,462	—	31,467
	\$856,429	\$14,623	\$(2,769)	\$868,283

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of December 31, 2016 mature at various dates through November 2021. The fair values of debt security investments by contractual maturity consist of the following:

	As of December 31,	
	2016	2015
Maturities within one year	\$503,482	\$236,121
Maturities after one year through five years	815,040	600,695
	\$1,318,522	\$836,816

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
As of December 31, 2016						
Corporate bonds	\$759,222	\$(4,685 )	\$36,407	\$ (58 )	\$795,629	\$(4,743 )
U.S. government and government agency obligations	81,170	(641 )	—	—	81,170	(641 )
Municipal bonds	7,141	(20 )	—	—	7,141	(20 )
Equity securities	36,417	(13,583 )	—	—	36,417	(13,583 )
	\$883,950	\$(18,929 )	\$36,407	\$ (58 )	\$920,357	\$(18,987 )
As of December 31, 2015						
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 )

During the year ended December 31, 2016, the Company recorded an other-than-temporary impairment charge of \$9.8 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 on sales of marketable securities were not material for the years ended December 31, 2016 and 2015. For the year ended December 31, 2014, total realized gains on sales of marketable securities were not material and there were no realized losses.

Changes in the Company's accumulated other comprehensive income (loss) for the years ended December 31, 2016, 2015, and 2014 related to unrealized gains and losses on available-for-sale marketable securities. For the years ended December 31, 2016, 2015, and 2014, amounts reclassified from accumulated other comprehensive income (loss) into other income (expense), net in the Company's Consolidated Statements of Operations were related to the 2016 impairment charge on the equity security and realized gains and losses on sales of marketable securities described above.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 6. Fair Value Measurements

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

	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)
As of December 31, 2016			
Available-for-sale marketable securities:			
Corporate bonds	\$ 1,072,851	—	\$ 1,072,851
U.S. government and government agency obligations	132,340	—	132,340
Municipal bonds	7,644	—	7,644
Commercial paper	63,075	—	63,075
Certificates of deposit	42,612	—	42,612
Equity securities	49,219	\$ 49,219	—
	\$ 1,367,741	\$ 49,219	\$ 1,318,522

As of December 31, 2015

Available-for-sale marketable securities:

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	31,467	\$ 31,467	—
	\$ 868,283	\$ 31,467	\$ 836,816

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 2016, 2015, and 2014.

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, 2016 and 2015. During 2016, transfers of marketable securities from Level 2 to Level 1 were \$44.1 million in connection with the lapse of transfer restrictions in November 2016 on the Company's investment in Intellia common shares. 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 in January 2015 on the Company's investment in Adverum Biotechnologies, Inc. (formerly Avalanche Biotechnologies, Inc.) common shares. 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 years ended December 31, 2016 and 2015.

As of December 31, 2015, the Company had \$11.2 million in aggregate principal amount of 1.875% convertible senior notes outstanding that matured in October 2016 (see Note 11). The fair value of the outstanding convertible senior notes was estimated to be \$72.8 million as of December 31, 2015, and was determined based on Level 2 inputs, such as market and observable sources.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 7. Inventories

Inventories consist of the following:

	As of December 31,	
	2016	2015
Raw materials	\$92,287	\$59,151
Work-in-process	202,301	132,068
Finished goods	13,334	11,197
Deferred costs	91,434	36,162
	\$399,356	\$238,578

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). For the years ended December 31, 2016, 2015, and 2014, cost of goods sold included inventory write-downs and reserves totaling \$14.0 million, \$10.6 million, and \$6.0 million, respectively.

## 8. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	As of December 31,	
	2016	2015
Land	\$103,906	\$77,826
Building and improvements	1,278,283	760,517
Leasehold improvements	101,101	95,226
Construction-in-progress	318,929	579,834
Laboratory and other equipment	554,181	330,432
Furniture, computer and office equipment, and other	152,525	81,381
	2,508,925	1,925,216
Less, accumulated depreciation and amortization	(425,504 )	(331,096 )
	\$2,083,421	\$1,594,120

As of December 31, 2016 and 2015, \$1,441.2 million and \$1,118.4 million, respectively, of the Company's property, plant, and equipment was located in the United States and \$642.2 million and \$475.7 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 \$104.7 million, \$74.9 million, and \$52.7 million for the years ended December 31, 2016, 2015, and 2014, respectively.

Property, plant, and equipment, at cost, as of December 31, 2016 and 2015 included \$269.0 million and \$254.6 million, respectively, of costs incurred by the Company's landlord to construct laboratory and office facilities in Tarrytown, New York. Additionally, property, plant, and equipment, at cost, as of December 31, 2016 included \$138.1 million of leased property under a capital lease. See Note 12a.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	As of December 31,	
	2016	2015
Accounts payable	\$134,984	\$140,962
Accrued payroll and related costs	153,086	133,223
Accrued clinical trial expense	91,753	88,297
Accrued sales-related charges, deductions, and royalties	159,985	195,986
Income taxes payable	235,776	—
Other accrued expenses and liabilities	103,512	85,644
	\$879,096	\$644,112

## 10. Deferred Revenue

Deferred revenue consists of the following:

	As of December 31,	
	2016	2015
Current portion:		
Received or receivable from Sanofi (see Note 3a)	\$115,267	\$101,573
Received or receivable from Bayer (see Note 3b)	31,084	24,290
Received or receivable from MTPC (see Note 3c)	9,188	2,352
Received or receivable from Teva (see Note 3d)	43,122	—
Received for technology license agreement (see Note 4)	23,572	23,572
Other	9,431	1,700
	\$231,664	\$153,487
Long-term portion:		
Received or receivable from Sanofi (see Note 3a)	\$503,474	\$582,664
Received or receivable from Bayer (see Note 3b)	77,028	31,926
Received or receivable from MTPC (see Note 3c)	45,940	7,059
Received or receivable from Teva (see Note 3d)	194,050	—
Received for technology license agreement (see Note 4)	10,280	33,851
Other	—	9,179
	\$830,772	\$664,679

## 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 paid interest semi-annually on April 1 and October 1, and matured on October 1, 2016. The Notes were 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 was approximately \$84.02 per share.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 was 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 was 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 covered, subject to customary anti-dilution adjustments, the number of shares of the Company's Common Stock that initially underlie the Notes, and were intended to reduce the potential dilutive impact of the conversion feature of the Notes. The convertible note hedge terminated upon the earlier of the maturity date of the Notes or the first day the Notes were 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 had an initial strike price of approximately \$103.41 per share, could be settled in cash or shares of the Company's Common Stock, at the Company's option, and were to become exercisable at various dates during 2017. Proceeds received from the warrant transactions totaled \$93.8 million and were recorded as additional paid-in capital. 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.

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. In 2015, the Company also recognized a \$18.9 million loss on the debt extinguishment. In connection with the Note conversions in 2015, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 1,625,088 shares 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, as Treasury Stock during 2015.

During 2016, the Company settled conversion obligations for \$12.9 million principal amount of the Company's Notes. Consequently, in 2016, the Company paid \$12.9 million in cash and issued 121,058 shares of Common Stock. In addition, the Company allocated \$47.8 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. The loss on the debt extinguishment in connection with the Notes that were surrendered for conversion during 2016 was not material. As a result of these Note conversions, the Company also exercised a proportionate amount of its convertible note hedges during 2016, for which the Company received 121,048 shares 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 \$10.2 million, as Treasury Stock during 2016.

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

	As of
	December
	31,
	2020
Total convertible senior notes - par	\$11,154
Unamortized discount	(352 )
	\$10,802

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

Total interest expense associated with the Notes, net of capitalized interest as applicable, consists of the following:

	Year Ended December		
	31,		
	2016	2015	2014
Contractual coupon interest rate	\$7	\$544	\$5,036
Amortization of discount and note issuance costs	150	2,818	17,821
	\$157	\$3,362	\$22,857

## 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. 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. 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 and the estimated fair value of the remaining liability as of December 31, 2014 was \$87.5 million, which was recorded within other current liabilities within the Company's Consolidated 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. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. 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. 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. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. 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 in the first quarter of 2016 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).

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. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. 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.

In February 2016, 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 975,142. 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,

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

provided that the warrant holder did not effect any purchases at a price per share exceeding \$375.00 per share, during the period starting on February 22, 2016 and ending no later than May 5, 2016. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. As a result of the warrant holder closing out a portion of its hedge position, the Company paid a total of \$106.9 million to reduce the number of warrants held by such warrant holder by 403,665.

In November 2016, the Company and warrant holders entered into warrant termination agreements whereby the parties agreed to cancel the remaining warrants held by the warrant holders and to terminate the respective warrant agreements in consideration for payments by the Company of \$401.2 million in the aggregate. The Company made the termination payments in the fourth quarter of 2016, and, as a result, no warrants remained outstanding as of December 31, 2016.

## 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, 2016. 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, 2016.

## 12. Commitments and Contingencies

## a. Leases

## Descriptions of Lease Agreements

The Company leases laboratory and office facilities in Tarrytown, New York (the "Tarrytown Leases"). 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, (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, and (v) under a June 2015 lease agreement, an existing building ("Building F") that the Company intends to renovate for additional laboratory and office space. The lease agreements related to Buildings A, B, C, D, E, and F (collectively, the "Buildings") expire in 2029; the remaining facilities under the lease expire in June 2024. The Tarrytown Leases provide for monthly payments over their respective terms and additional charges for utilities, taxes, and operating expenses.

Historically, certain of the premises under the Tarrytown Leases had been 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.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

On December 30, 2016, the Company entered into a Purchase Agreement with BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC (collectively, "BMR"), pursuant to which the Company agreed to purchase BMR's Tarrytown, New York facilities (the "Facility") for a purchase price of \$720.0 million, subject to certain customary adjustments. The Company currently occupies a significant portion of the Facility, with the remaining rentable area, or approximately 300,000 square feet, under leases to third-party tenants. In accordance with the terms of the Purchase Agreement, the Company paid \$57.0 million toward the purchase price to BMR in December 2016. The closing of the Purchase Agreement is anticipated in the first quarter of 2017.

The Company intends to fund the acquisition contemplated by the Purchase Agreement with a new financing. Accordingly, the Company has entered into an engagement letter with Banc of America Leasing & Capital, LLC ("BAL"), pursuant to which BAL has been engaged to use its best efforts to arrange a \$720.0 million lease financing in connection with the acquisition contemplated by the Purchase Agreement. As part of the contemplated financing, the Company intends to assign some or all its rights under the Purchase Agreement (including the right to take title to the Facility) to an affiliate of BAL at the closing of the financing, as a result of which such affiliate will become the legal owner of the Facility (the "Lessor"). Upon assignment of its rights, the Company expects to be reimbursed by BAL or an affiliate of BAL for the \$57.0 million payment the Company made in December 2016. Immediately thereafter, the Company intends to lease the Facility from the Lessor for a term of five years. At the end of the lease term, the Company expects to have an option to extend the term of the lease (subject to the consent of the financing providers), purchase the Facility at a predetermined amount, or sell the Facility to a third party on behalf of the Lessor. While the Company has engaged BAL to use its best efforts to arrange a financing in connection with the contemplated Purchase Agreement, there is no guarantee that the Company will be able to obtain such financing on the agreed terms or at all.

Upon entering into the Purchase Agreement with BMR, the premises under the Company's Tarrytown Leases that were historically accounted for as operating leases were deemed to be modified, as the Company now has the option to purchase the facility, under terms that make it reasonably assured to be exercised. Consequently, the leases for such premises have been re-classified as a capital lease upon execution of the Purchase Agreement, and a proportionate amount of the \$57.0 million payment was recorded as reduction of the initial capital lease liability. The execution of the Purchase Agreement did not impact the balance sheet classification for the Buildings; however, a proportionate amount of the \$57.0 million payment was recorded as a reduction of the existing facility lease obligation.

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

**Commitments under Operating Leases**

The estimated future minimum noncancelable lease commitments under operating leases, as of December 31, 2016, are as follows:

	Facilities	Equipment	Total
2017	\$ 4,728	\$ 5,156	\$ 9,884
2018	4,860	825	5,685
2019	4,817	273	5,090
2020	4,271	12	4,283
2021	3,982	11	3,993
Thereafter	22,336	—	22,336
	\$ 44,994	\$ 6,277	\$ 51,271

Rent expense under operating leases was:

Year Ended December 31,	Facilities	Equipment	Total
2016	\$ 15,861	\$ 852	\$ 16,713
2015	14,659	543	15,202

2014	13,360	952	14,312
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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## Capital Leases

As described above, the Company's Tarrytown Leases that had been historically accounted for as operating leases were re-classified as capital leases upon entering into the Purchase Agreement on December 30, 2016. The estimated future minimum noncancelable lease commitments under these capital leases, as of December 31, 2016, was not material as the Company anticipates closing of the Purchase Agreement in the first quarter of 2017. The Company had no additional capital leases as of December 31, 2016.

At December 31, 2016, capital lease obligations of \$127.3 million were included in the Company's Consolidated Balance Sheet.

## 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 Consolidated 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 12%. 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 11%. 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%. With respect to Building F, the building was placed in service by the Company in 2016 and monthly lease payments do not commence until 2017. The imputed interest rate applicable to the Company's Buildings F facility lease obligation is approximately 10%. In 2016, 2015, and 2014, the Company recognized \$5.4 million, \$9.7 million, and \$14.5 million, respectively, of interest expense in connection with the Buildings' facility lease obligations.

Facility lease obligations consist of the following:

	As of December 31,	
	2016	2015
Buildings A and B	\$99,323	\$108,857
Building C	44,338	49,475
Buildings D and E	194,037	206,376
Building F	16,154	—
	\$353,852	\$364,708

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2016, exclusive of the potential impact of the closing of the Purchase Agreement (which is anticipated to occur in the first quarter of 2017), are as follows:

	Buildings A and B	Building C	Buildings D and E	Building F	Total
2017	\$13,965	\$4,740	\$12,922	\$490	\$32,117
2018	14,242	4,873	13,267	759	33,141
2019	14,526	5,009	13,621	786	33,942
2020	14,818	5,149	13,983	813	34,763
2021	15,116	5,292	14,354	841	35,603
Thereafter	101,010	48,801	121,927	7,190	278,928
	\$173,677	\$73,864	\$190,074	\$10,879	\$448,494

## 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 once the applicable collaboration becomes profitable. See Note 3. 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 \$400.0 million, and was obligated to pay royalties of 4.75% on cumulative U.S. sales of EYLEA between \$400.0 million and \$3.0 billion and 5.5% on any cumulative U.S. sales of EYLEA over \$3.0 billion. As the Company recorded net product sales of EYLEA, the Company recognized expense in connection with the Genentech Agreement using a blended mid-single digit royalty rate that reflected both the \$60.0 million payment and the royalties payable on cumulative sales and that was 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 the Amended Genentech Agreement, the Company was 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 under the Company's license and collaboration agreement. All payments to Genentech



under the Original Genentech Agreement and the Amended Genentech Agreement were made by the Company, and Bayer shared 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's obligation to pay royalties pursuant to the Original Genentech Agreement and Amended Genentech Agreement terminated on May 7, 2016, when the licenses granted to the Company thereunder became fully paid up and royalty free for the duration of the remaining term of the underlying patents.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

For the years ended December 31, 2016, 2015, and 2014, the Company recorded royalty expense of \$125.3 million, \$247.9 million, and \$169.9 million, respectively, based on product sales of commercial products under various licensing agreements (including the Genentech agreements described above).

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 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 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 connection with the Company's license and collaboration agreements with Bayer for the joint development and commercialization outside the United States of antibody product candidates to PDGFR-beta and Ang2 (see Note 3b), Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of the Company or acquiring more than 20% of the Company's outstanding shares of Class A Stock and

Common Stock (taken together). With respect to each of these agreements, 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.

Further, pursuant to the 2016 Teva Collaboration Agreement, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of the Company or acquiring more than 5% of the Company's 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 Company's announcement recommending acceptance by the Company's shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving the Company; (iii) the public announcement of any definitive agreement providing for a change of control

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

involving the Company; (iv) the acquisition of more than 30% of the voting power of the Company's then outstanding Class A Stock and Common Stock (taken together); (v) the date of any issuance of shares of capital stock by the Company that would result in another party having more than 10% of the voting power of the Company's 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 Teva; or (vi) other specified events, such as a liquidation or dissolution of the Company.

In October 2011, the Company completed a private placement of \$400.0 million aggregate principal amount of Notes, which were 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 2016, 2015, and 2014, the Company elected to settle Notes which were surrendered for conversion 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. 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 2016, 2015, and 2014, the Company entered into agreements and made payments to reduce the number of warrants held 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.

**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.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 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, 2016, there were 6,408,989 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 2016 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
Outstanding as of December 31, 2015	23,165,769	\$ 236.75		
2016: Granted	4,201,978	\$ 386.44		
Forfeited	(468,798 )	\$ 398.57		
Expired	(20,645 )	\$ 420.04		
Exercised	(1,742,277 )	\$ 76.79		
Outstanding as of December 31, 2016	25,136,027	\$ 269.69	6.66	\$3,399,815
Vested and expected to vest as of December 31, 2016	24,598,430	\$ 266.16	6.60	\$3,397,437
Exercisable as of December 31, 2016	15,140,287	\$ 166.96	5.19	\$3,299,296

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 2016, 2015, and 2014 was \$550.4 million, \$1,031.6 million, and \$1,081.2 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.



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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The Company grants stock options with exercise prices that are equal to or greater than the average market price of the Company's Common Stock on the date of grant ("Market Price"). The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2016, 2015, and 2014. 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
2016:			
Exercise price equal to Market Price	4,201,978	\$ 386.44	\$ 126.68
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

For the years ended December 31, 2016, 2015, and 2014, the Company recognized \$546.0 million, \$443.7 million, and \$306.1 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards. As of December 31, 2016, there was \$888.0 million of stock-based compensation cost related to outstanding non-performance based stock options, net of estimated forfeitures, which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.9 years.

For the year ended December 31, 2014, the Company recognized \$4.1 million of non-cash stock-based compensation expense related to performance-based options. The Company has not issued any performance-based options since 2011, and such options became fully vested during 2014.

## Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2016, 2015, and 2014.

	2016	2015	2014
Expected volatility	34	% 35	% 39
Expected lives from grant date	5.1 years	5.1 years	5.2 years
Expected dividend yield	0	% 0	% 0
Risk-free interest rate	1.84	% 1.68	% 1.62

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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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards during 2016 is summarized below:

Restricted Stock:	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2015	541,700	\$ 133.96
2016: Granted	16,750	\$ 385.84
Vested	(11,590 )	\$ 125.38
Forfeited	(40 )	\$ 237.68
Outstanding as of December 31, 2016	546,820	\$ 141.85

The Company recognized non-cash stock-based compensation expense from Restricted Stock awards of \$13.9 million, \$15.3 million, and \$11.5 million in 2016, 2015, and 2014, respectively. As of December 31, 2016, there was \$26.0 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 1.2 years.

## 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 (as defined by the Savings Plan) 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 \$17.7 million, \$15.4 million, and \$13.1 million of Contribution expense in 2016, 2015, and 2014, 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 2016, 2015, and 2014.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 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,		
	2016	2015	2014
United States	\$1,650,959	\$1,665,087	\$1,101,446
Foreign	(321,144 )	(439,990 )	(340,211 )
	\$1,329,815	\$1,225,097	\$761,235

Components of income tax expense consist of the following:

	Year Ended December 31,		
	2016	2015	2014
Current:			
Federal	\$786,964	\$686,561	\$437,038
State	8,769	28,568	28,718
Foreign	(1,362 )	4,004	2,879
Total current tax expense	794,371	719,133	468,635
Deferred:			
Federal	(377,368 )	(119,849 )	(62,932 )
State	13,431	(3,768 )	18,891
Foreign	3,859	(6,475 )	(1,485 )
Total deferred tax (benefit) expense	(360,078 )	(130,092 )	(45,526 )
	\$434,293	\$589,041	\$423,109

In 2015 and 2014, the Company utilized \$405.3 million and \$439.3 million of excess tax benefits in connection with stock option exercises, which were credited to additional paid-in capital as realized. The Company elected to early adopt ASU 2016-09 during the second quarter of 2016. Consequently, in 2016, the Company recorded excess tax benefits of \$144.8 million within income tax expense. See Note 1. "Business Overview and Summary of Significant Accounting Policies - Recently Issued Accounting Standards."

The Company also recorded an income tax benefit in its Statement of Comprehensive Income of \$3.3 million during the year ended December 31, 2016 and an income tax provision of \$24.9 million and \$27.1 million during the years ended December 31, 2015 and 2014, respectively, primarily related to unrealized gains (losses) on available-for-sale marketable securities.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

	Year Ended December		
	31,		
	2016	2015	2014
U.S. federal statutory tax rate	35.0 %	35.0 %	35.0 %
Stock-based compensation	(10.9)	—	—
State and local income taxes	0.3	1.0	2.4
Change in state effective rate	1.0	(0.1 )	2.9
Foreign income tax rate differential	8.8	12.2	15.8
Income tax credits	(1.2 )	(1.6 )	(5.1 )
Non-deductible Branded Prescription Drug Fee	1.9	2.0	2.8
Domestic production activities deduction	(2.8 )	(3.2 )	—
Other permanent differences	0.6	2.8	1.8
Effective income tax rate	32.7 %	48.1 %	55.6 %

In 2016, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 32.7% was primarily attributable to the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for research activities, offset by the negative impact of 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 2015, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 48.1% was 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.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

	As of December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforward	\$137	\$140
Fixed and intangible assets	21,139	—
Deferred revenue	214,587	51,766
Deferred compensation	515,984	349,508
Capitalized research and development costs	2,492	7,725
Accrued expenses	37,188	47,520
Other	46,471	26,580
	837,998	483,239
Valuation allowance	(3,420 )	—
Total deferred tax assets	834,578	483,239

## Deferred tax liabilities:

Unrealized gains/losses on marketable securities	—	(3,280 )
Fixed assets and intangible assets	—	(5,559 )
Other	(9,275 )	(12,455 )
Total deferred tax liabilities	(9,275 )	(21,294 )
Net deferred tax assets	\$825,303	\$461,945

The Company's 2012 through 2015 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 2013 to 2015 remain open to examination. 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.

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 \$107.2 million, \$102.1 million, and \$51.2 million as of December 31, 2016, 2015, and 2014, respectively.

	2016	2015	2014
Balance as of January 1	\$116,572	\$57,615	\$26,627
Gross increases related to current year tax positions	45,575	59,909	27,538
Gross (decreases) increases related to prior year tax positions	(42,284 )	(952 )	6,464
Gross decrease due to settlements, recapture, filed returns, and lapse of statutes of limitation	(2,697 )	—	(3,014 )
Balance as of December 31	\$117,166	\$116,572	\$57,615

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

In 2016 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 2016, the Company accrued interest of \$3.3 million related to its unrecognized tax benefits. In 2015 and 2014, accrued interest related to unrecognized tax benefits recorded by the Company was not material. The Company believes that it is reasonably possible that its unrecognized tax benefits as of December 31, 2016 may decrease by up to \$22.3 million within the next twelve months related to the resolution of state tax exposures.

## 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. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted.

## Proceedings Relating to '287 Patent, '163 Patent, and '018 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 engineered 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 estimate possible gain or a range of possible loss, if any, related to, these proceedings.

## Proceedings Relating to Praluent (alirocumab) Injection

As described in greater detail below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. against the Company and Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent, which the Company is jointly developing and commercializing with Sanofi.

In the United States, Amgen has asserted a number of U.S. patents, which were subsequently narrowed to U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and seeks a permanent injunction to prevent the Company and the Sanofi defendants from manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, "Commercializing") Praluent. 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. A jury trial in this litigation was held in the United States District Court for the District of Delaware from March 8 to March 16, 2016. During the course of the trial, the court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of the Company and the Sanofi defendants that there was no willful infringement of the asserted patent claims by the Company or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On January 3, 2017, the court issued a final opinion and judgment, denying the Company and the Sanofi defendants' motions for new trial and judgment as a matter of law. The court also denied as moot Amgen's motion to strike the Company and the Sanofi defendants' request to obtain a judgment as a matter of law, which allows the U.S. Court of Appeals for the Federal

Circuit to address the Company and the Sanofi defendants' patent invalidity arguments on appeal. On January 12, 2017, the Company and the Sanofi defendants filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. On January 18, 2017, the U.S. Court of Appeals for the Federal Circuit ordered an expedited briefing schedule of the appeal on the merits, pursuant to which the briefing is scheduled to be completed no later than March 31, 2017. On January 31, 2017, Amgen filed a motion with the United States District Court for the District of Delaware to amend the court's final judgment to include an award of supplemental damages (including interest) and enhancement of such damages following the resolution of the appeal.

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

On March 23 and March 24, 2016, the United States District Court for the District of Delaware held a permanent injunction hearing to determine whether Regeneron and the Sanofi defendants should be prohibited from Commercializing Praluent in the United States. On January 5, 2017, the court granted the permanent injunction but delayed its imposition for 30 days (subsequently extended to 45 days) from the date of grant (i.e., until February 21, 2017). On January 13, 2017, the Company and the Sanofi defendants filed an emergency motion for stay of the permanent injunction pending appeal with the U.S. Court of Appeals for the Federal Circuit; and, on February 8, 2017, the court granted the stay pending appeal.

On July 25, 2016, Amgen filed a lawsuit against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of Amgen's European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, by Praluent. The lawsuit also seeks a permanent injunction, damages, an accounting of profits, and costs and interest. On February 8, 2017, the court temporarily stayed this litigation on terms mutually agreed by the parties.

Also on July 25, 2016, Amgen filed a lawsuit for infringement of the '124 Patent against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf, Germany, seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages. Oral hearing on this infringement lawsuit is currently scheduled for October 19, 2017.

On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against Regeneron, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie. Amgen is seeking the prohibition of allegedly infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time.

At this time, the Company is not able to predict the outcome of, or 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 ("Sanofi-Aventis") 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, 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 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 (the "'415 Patent" and, together, with the "221 Patent", the "Cabilly Patents") 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 of the '415 Patent for which review had been requested. On August 18, 2016, Regeneron and Sanofi-Aventis entered into a License and Settlement Agreement with Genentech and City of Hope that resolved all outstanding issues concerning the Cabilly Patents in the above-referenced litigation and inter partes review proceeding, resulting in a joint stipulation of dismissal being entered in the court and the USPTO. Under the agreement, Regeneron has been granted a license to the Cabilly Patents to make, use, and sell Praluent and all other antibody products under development at the time of the settlement.

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REGENERON PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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. On March 2, 2016, the defendants filed a motion to dismiss the shareholder derivative complaint. On August 16, 2016, the court heard oral argument on defendants' motion to dismiss.

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

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

Department of Justice Investigation

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST, and ZALTRAP); and certain other related documents and communications. The Company is cooperating with this investigation. The Company cannot predict the outcome or duration of these investigations or any other legal proceedings or any enforcement actions or other remedies that may be imposed on the Company arising out of these investigations.

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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## 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,		
	2016	2015	2014
Net income - basic	\$895,522	\$636,056	\$338,126
Effect of dilutive securities:			
Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs	397	—	—
Net income - diluted	\$895,919	\$636,056	\$338,126
(Shares in thousands)			
Weighted average shares - basic	104,719	103,061	100,612
Effect of dilutive securities:			
Stock options	10,177	9,446	9,440
Restricted stock	474	477	425
Convertible senior notes	61	—	—
Warrants	936	2,246	2,936
Dilutive potential shares	11,648	12,169	12,801
Weighted average shares - diluted	116,367	115,230	113,413
Net income per share - basic	\$8.55	\$6.17	\$3.36
Net income per share - diluted	\$7.70	\$5.52	\$2.98

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)	2016	2015	2014
Stock options	8,041	1,343	1,470
Restricted stock	19	—	—
Convertible senior notes	—	994	4,247

## 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, 2016, 2015, and 2014 were \$28.2 million, \$50.7 million, and \$56.2 million, respectively, of accrued capital expenditures.

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, 2016 and 2015.



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## REGENERON PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The Company recognized an additional facility lease obligation of \$16.8 million, \$26.0 million, and \$127.8 million during 2016, 2015, and 2014, 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). In addition, during 2016, the Company recognized capital lease obligations of \$138.1 million in connection with the modification of the Company's Tarrytown Leases (see Note 12a).

## 20. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2016 and 2015 are set forth in the following tables.

	First Quarter Ended March 31, 2016*	Second Quarter Ended June 30, 2016	Third Quarter Ended September 30, 2016	Fourth Quarter Ended December 31, 2016
	(Unaudited)			
Revenues	\$1,200,849	\$1,212,629	\$1,220,122	\$1,226,827
Net income	\$181,385	\$196,218	\$264,804	\$253,115
Net income per share - basic	\$1.74	\$1.88	\$2.53	\$2.41
Net income per share - diluted	\$1.59	\$1.69	\$2.27	\$2.19

	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

\* Due to the adoption of ASU 2016-09, the Company revised its net income from the amounts originally reported for the quarterly period ended March 31, 2016 to include a \$15.6 million income tax benefit, which was originally recorded as additional paid-in capital.