REGENERON PHARMACEUTICALS INC
Form 10-K
February 07, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark
One)
ANNUAL
REPORT
PURSUANT
TO SECTION
ý 13 OR 15(d)
OF THE
SECURITIES
EXCHANGE
ACT OF 1934
For the fiscal
year ended
December 31,
2018
OR
TRANSITION
REPORT
PURSUANT
TO SECTION
¨ 13 OR 15(d)
OF THE
SECURITIES
EXCHANGE
ACT OF 1934
For the
transition
period from
_____
to
_____
Commission File Number: 0-19034
REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

(914) 847-7000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered

Common Stock - par value $.001 per share	NASDAQ Global Select Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes ý No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.	Yes ¨ No ý
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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).	Yes ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.	..

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	ý	Accelerated filer	¨	Non-accelerated filer	¨	Smaller reporting company	..
Emerging growth company	¨						

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.	¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).	Yes ¨ No ý

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was approximately $35,741,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 29, 2018, 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 January 31, 2019:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,911,354
Common Stock, $.001 par value	107,365,835

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2019 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 78 to 83 of this filing.

Table of Contents

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

		Page Numbers
PART I		
Item 1.	Business	2
Item 1A.	Risk Factors	30
Item 1B.	Unresolved Staff Comments	57
Item 2.	Properties	57
Item 3.	Legal Proceedings	58
Item 4.	Mine Safety Disclosures	58
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	59
Item 6.	Selected Financial Data	60
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	61
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	76
Item 8.	Financial Statements and Supplementary Data	77
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	77
Item 9A.	Controls and Procedures	77
Item 9B.	Other Information	78
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	78
Item 11.	Executive Compensation	78
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	78
Item 13.	Certain Relationships and Related Transactions, and Director Independence	78
Item 14.	Principal Accounting Fees and Services	78
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	78
Item 16.	Form 10-K Summary	83
SIGNATURE PAGE		84

"ARCALYST®", "EYLEA®", "Libtayo®" (in the United States), "Regeneron®", "Regeneron Genetics Center®", "Veloci-Bi™", "VelociGene®", "VelociMab®", "VelocImmune®", "VelociMouse®", "VelociSuite®", and "ZALTRAP®" 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.

Table of Contents

PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "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® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Libtayo® (cemiplimab) Injection, fasinumab, and evinacumab; the likelihood and timing of achieving any of our anticipated clinical development milestones and the impact of the recent and any potential future U.S. government shutdowns on the anticipated timing of any U.S. Food and Drug Administration regulatory action referenced in this report; 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, Dupixent, Praluent, Kevzara, Libtayo, fasinumab, and evinacumab; the extent to which the results from the research and development programs conducted by us or our collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo), 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; the ability of our collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to our products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our 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 proceedings relating to EYLEA, Dupixent, and Praluent described further in Note 17 to our Consolidated Financial Statements included in 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 biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. Our commercialized medicines and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neuromuscular diseases, infectious diseases, and rare diseases.

Selected financial information is summarized as follows:

Year Ended December 31,

(In millions, except per share data)	2018	2017	2016
Revenues	$6,710.8	$5,872.2	$4,860.4
Net income	$2,444.4	$1,198.5	$895.5
Net income per share - diluted	$21.29	$10.34	$7.70

Table of Contents

Marketed Products

We currently have seven products that have received marketing approval:

Product	Disease Area[1]	Territory			
		U.S.	EU	Japan	Certain other countries outside the U.S.
EYLEA (aflibercept) Injection[2]	Neovascular age-related macular degeneration (wet AMD)	a	a	a	a
	Diabetic macular edema (DME)	a	a	a	a
	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)	a	a	a	a
	Myopic choroidal neovascularization (mCNV)		a	a	a
	Diabetic retinopathy in patients with DME	a			
Dupixent (dupilumab) Injection[3]	Atopic dermatitis (in adults)	a	a	a	a
	Asthma (in adults and adolescents)	a			
Praluent (alirocumab) Injection[3]	Heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) (in adults)	a	a	a	a
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	Rheumatoid arthritis (RA) (in adults)	a	a	a	a
Libtayo (cemiplimab) Injection[3][5]	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	a			
ARCALYST® (rilonacept) Injection for Subcutaneous Use	Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)	a			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[4]	Metastatic colorectal cancer (mCRC)	a	a	a	a

[1] Refer to label information in each territory for specific indication

[2] In collaboration with Bayer (outside the United States)

[3] In collaboration with Sanofi

[4] Pursuant to a 2015 amended and restated 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

[5] Marketed as Libtayo (cemiplimab-rwlc) Injection in the United States

Table of Contents

Net Product Sales of Regeneron-Discovered Products[2]	Year Ended December 31,								
(In millions)	2018			2017			2016		
	U.S.	ROW[1]	Total	U.S.	ROW[1]	Total	U.S.	ROW[1]	Total
EYLEA[2]	$4,076.7	$2,668.9	$6,745.6	$3,701.9	$2,226.9	$5,928.8	$3,323.1	$1,872.3	$5,195.4
Libtayo	14.8	—	14.8	—	—	—	—	—	—
ARCALYST	14.7	—	14.7	16.6	—	16.6	15.3	—	15.3
Net product sales recorded by Regeneron	$4,106.2			$3,718.5			$3,338.4		
Net product sales recorded by Sanofi[2]:									
Dupixent	$776.3	$145.7	$922.0	$253.8	$2.7	$256.5	—	—	—
Praluent	$181.3	$125.5	$306.8	$131.4	$63.3	$194.7	$94.4	$21.9	$116.3
Kevzara	$74.7	$21.9	$96.6	$11.6	$1.7	$13.3	—	—	—
ZALTRAP	$9.0	$98.8	$107.8	$10.7	$73.1	$83.8	$16.6	$55.7	$72.3

[1] Rest of world
[2] Bayer records net product sales of EYLEA outside the United States and Sanofi records global net product sales of Dupixent, Praluent, Kevzara, and ZALTRAP. Refer to "General" above and "Collaboration Agreements" below for further details.

Programs in Clinical Development

All 21 of our product candidates in clinical development were discovered in our research laboratories and are summarized below. We used our VelocImmune® technology to generate each of the antibodies in the table below. There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, and changes in the competitive landscape affecting a product candidate. Refer to Item 1A. "Risk Factors" for a description of these and other risks and uncertainties that may affect our clinical programs.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
EYLEA			Non-proliferative diabetic retinopathy (NPDR) in patients without DME	Diabetic retinopathy (U.S.)
Dupixent (dupilumab)[a] Antibody to IL-4R alpha subunit		Grass allergy Peanut allergy	Atopic dermatitis in adolescents and pediatrics (6–11 years of age)[d]	Asthma in adults and adolescents (EU and Japan)
			Atopic dermatitis in pediatrics (6 months–5 years of age) (Phase 2/3)[d]	Atopic dermatitis in adolescents (12–17 years of age) (U.S. and EU)
			Asthma in pediatrics (6–11 years of age)	Auto-injector for 200 mg dose (U.S. and EU)
			Eosinophilic esophagitis (EOE) (Phase 2/3)[c]	Chronic rhinosinusitis with nasal polyposis (CRSwNP) (U.S.)

Table of Contents

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
Praluent (alirocumab)[a] Antibody to PCSK9			Homozygous familial hypercholesterolemia (HoFH)[c] in adults and pediatrics	Cardiovascular risk reduction (U.S. and EU)
			HeFH in pediatrics	First-line treatment of hyperlipidemia (U.S.)
Kevzara (sarilumab)[a] Antibody to IL-6R		Polyarticular-course juvenile idiopathic arthritis (pcJIA)	Polymyalgia rheumatica	
		Systemic juvenile idiopathic arthritis (sJIA)	Giant cell arteritis	
Libtayo (cemiplimab)[a] Antibody to PD-1[h]	Solid tumors and advanced hematologic malignancies	Metastatic or locally advanced CSCC[d]	First-line non-small cell lung cancer (NSCLC)	Metastatic or locally advanced CSCC (EU)
		Basal cell carcinoma (BCC) (potentially pivotal study)	Second-line cervical cancer	
Fasinumab[b][f] (REGN475) Antibody to NGF			Osteoarthritis of knee and hip[e]	
Evinacumab[f] (REGN1500) Antibody to ANGPTL3		Refractory hypercholesterolemia (both HeFH and non-FH)	HoFH[c][d]	
		Severe hypertriglyceridemia		
Garetosmab[f] (REGN2477) Antibody to Activin A	Muscle-wasting diseases (in combination with trevogrumab)	Fibrodysplasia ossificans progressiva (FOP)[c][e] (potentially pivotal study)		
REGN3500[a] Antibody to IL-33. Studied as monotherapy and in combination with Dupixent.		Asthma Chronic obstructive pulmonary disease (COPD) Atopic dermatitis		
Trevogrumab[f] (REGN1033) Antibody to myostatin (GDF8)	Muscle-wasting diseases (in combination with garetosmab)			
REGN1908-1909[f] Multi-antibody therapy to Feld1	Cat allergy			
REGN1979				

Bispecific antibody against CD20 and CD3	Certain B-cell malignancies (monotherapy and in combination with Libtayo)[c]
REGN-EB3[g] (REGN3470-3471-3479) Multi-antibody therapy to Ebola virus	Ebola virus infection[c]

Table of Contents

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review[i]
REGN3048-3051[g] Multi-antibody therapy to Middle East Respiratory Syndrome (MERS) virus	MERS virus infection			
REGN3767[f] Antibody to LAG-3 protein	Advanced cancers (administered alone or in combination with Libtayo)			
Pozelimab[f] (REGN3918) Antibody to C5	Paroxysmal nocturnal hemoglobinuria (PNH)			
REGN4461 Agonist antibody to leptin receptor (LEPR)	Lipodystrophy and obesity			
REGN4018[a] Bispecific antibody targeting MUC16 and CD3	Platinum-resistant ovarian cancer (administered alone or in combination with Libtayo)			
REGN4659[f] Antibody to CTLA4	Advanced NSCLC (administered alone or in combination with Libtayo)			
REGN5069 Antibody to GFR 3	Pain			
REGN5458[a] Bispecific antibody targeting BCMA and CD3	Multiple myeloma			

[a] In collaboration with Sanofi

[b] In collaboration with Teva and Mitsubishi Tanabe Pharma

[c] U.S. Food and Drug Administration (FDA) granted orphan drug designation

[d] FDA granted Breakthrough Therapy designation

[e] FDA granted Fast Track designation

[f] 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 global sales of the product candidate.
(g) 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. We and the Biomedical Advanced Research Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) are parties to agreements whereby HHS provides certain funding to support research, development, and manufacturing of these antibodies.

[h] Studied as monotherapy and in combination with other antibodies and treatments

[i] Regulatory application submitted. Information in this column relates to U.S., European Union (EU), and Japan submissions only.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to be an integrated, multi-product biotechnology company that provides patients and medical professionals with important 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 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.

Table of Contents

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2018 and 2019 to date were, and select 2019 milestones for the remainder of 2019 are, as follows:

Clinical Program	2018 and 2019 Events to Date	Select 2019 Milestones
EYLEA	Chinese State Food and Drug Administration (CFDA) approved EYLEA for DME and wet AMD Reported 24-week positive top-line results from Phase 3 PANORAMA study for the treatment of NPDR in patients without DME Reported that the Phase 3 PANORAMA study met its one-year primary endpoint and key secondary endpoints Submitted sBLA for the treatment of diabetic retinopathy FDA issued Complete Response Letter (CRL) regarding the sBLA for pre-filled syringe Treat and Extend dosing regimen approved in the EU for wet AMD FDA approved sBLA for every 12-week dosing regimen option after one year of effective therapy in patients with wet AMD FDA approved sBLA for vial-only presentation	FDA decision on sBLA for the treatment of diabetic retinopathy (target action date of May 13, 2019) Re-submission of Prior-Approval Supplement (PAS) for pre-filled syringe Initiate a study of a high dose formulation of aflibercept
Dupixent (dupilumab; IL-4R Antibody)	Ministry of Health, Labor and Welfare (MHLW) in Japan approved Dupixent for the treatment of atopic dermatitis in adults not adequately controlled with existing therapies Initiated Phase 2/3 study in pediatric patients (6 months–5 years of age) with severe atopic dermatitis Reported positive results from Phase 3 study in adolescent patients (12–17 years of age) with atopic dermatitis FDA accepted for priority review sBLA for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) Submitted Marketing Authorization Application (MAA) for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) FDA approved sBLA for moderate-to-severe asthma in patients 12 years of age and older Regulatory application for asthma accepted for review by the EMA and Pharmaceuticals and Medical Devices Agency (PMDA) in Japan Positive results from two Phase 3 trials for the treatment of moderate-to-severe asthma published in the New England Journal of Medicine Initiated Phase 2 study in grass allergy	FDA decision on sBLA for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) (target action date of March 11, 2019) Report results from Phase 3 study in pediatric patients (6–11 years of age) with atopic dermatitis European Medicines Agency (EMA) decision on regulatory application for asthma Initiate Phase 2/3 program in COPD FDA (target action date of March 11, 2019) and EMA decisions on applications for 200 mg auto-injector

7

Table of Contents

Clinical Program (continued)	2018 and 2019 Events to Date	Select 2019 Milestones
Dupixent (dupilumab; IL-4R Antibody) (continued)	Initiated Phase 2/3 study in eosinophilic esophagitis	
	Initiated Phase 2 study in peanut allergy Submitted sBLA for auto-injector for 200 mg dose Reported positive top-line results from both Phase 3 trials of patients with CRSwNP Submitted sBLA for CRSwNP	
Praluent (alirocumab; PCSK9 Antibody)	Reported positive results from ODYSSEY OUTCOMES study Submitted sBLA and MAA variation for cardiovascular risk reduction	FDA (target action date of April 28, 2019) and EMA decisions on applications for cardiovascular risk reduction
	European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) recommended approval for a new indication to reduce cardiovascular risk Submitted sBLA for first-line treatment of hyperlipidemia Initiated Phase 3 pediatric studies in HeFH and HoFH FDA approved sBLA for use with apheresis	FDA decision on sBLA for first-line treatment of hyperlipidemia (target action date of April 29, 2019)
Kevzara (sarilumab; IL-6R Antibody)	FDA approved sBLA for single-dose pre-filled pen presentation Initiated Phase 2 study in sJIA Initiated Phase 3 study in polymyalgia rheumatica Initiated Phase 3 study in giant cell arteritis	
Libtayo (cemiplimab; PD-1 Antibody)	EMA accepted for review MAA for advanced CSCC	Regulatory agency decision for advanced CSCC in the EU
	Positive results from pivotal trial in advanced CSCC published in the New England Journal of Medicine FDA approved BLA for the treatment of advanced CSCC Reported positive results from Phase 1 study in advanced NSCLC Initiated additional Phase 3 studies in advanced NSCLC	Continue patient enrollment in NSCLC and various other studies
Fasinumab (NGF Antibody)	Completed patient enrollment in the efficacy sub-study of the Phase 3 long-term safety study in osteoarthritis Independent Data Monitoring Committee (DMC) recommended higher dose-regimens be discontinued, and osteoarthritis trials modified accordingly Discontinued dosing in chronic low back pain in patients with concomitant osteoarthritis of the knee and hip	Continue patient enrollment in Phase 3 long-term safety study and Phase 3 efficacy studies in osteoarthritis

Reported positive top-line results from first Phase 3 efficacy study in osteoarthritis

Table of Contents

Clinical Program (continued)	2018 and 2019 Events to Date	Select 2019 Milestones
Evinacumab (ANGPTL3 Antibody)	Initiated Phase 3 study in HoFH Completed patient enrollment in Phase 3 study in HoFH Initiated Phase 2 study in severe hypertriglyceridemia	Report results from Phase 3 study in HoFH
Garetosmab (REGN2477; Activin A Antibody)	Initiated potentially pivotal Phase 2 study in patients with FOP	
REGN3500 (IL-33 Antibody)	Initiated Phase 2 study in asthma Completed patient enrollment in Phase 2 study in asthma Initiated Phase 2 study in COPD Initiated Phase 2 study in atopic dermatitis	Report results from Phase 2 study in asthma
Trevogrumab (GDF8 Antibody) in combination with garetosmab	Reported positive results from single-dose portion of Phase 1 study	Report results from multi-dose portion of Phase 1 study
REGN1908-1909 (Feld1 Antibody)		Initiate Phase 2 study in cat allergic asthmatics
REGN1979 (CD20 and CD3 Antibody)	FDA granted orphan drug designation in follicular lymphoma (FL)	Initiate potentially pivotal Phase 2 study in FL
	Presented positive results from Phase 1 study in patients with relapsed or refractory B-cell non-Hodgkin lymphoma at American Society of Hematology (ASH) Annual Meeting	Initiate potentially pivotal Phase 2 study in diffuse large B-cell lymphoma (DLBCL)
REGN-EB3 (REGN3470-3471-3479; Multi-antibody therapy to Ebola virus)	Being used investigationally in the Democratic Republic of the Congo in Ebola virus infection outbreak	
	Included in randomized controlled trial run by World Health Organization	
REGN3048-3051 (Multiple-antibody therapy to MERS)	Initiated Phase 1 study in healthy volunteers	Complete Phase 1 study in healthy volunteers
REGN3767 (LAG-3 Antibody)	Opened monotherapy expansion cohorts as well as in combination with Libtayo in multiple indications	
Pozelimab (REGN3918; C5 Antibody)	Completed Phase 1 study in healthy volunteers	Initiate Phase 2 study in PNH
REGN4461 (LEPR Agonist Antibody)	Initiated Phase 1 study in healthy volunteers	Initiate Phase 2 study in generalized lipodystrophy
REGN4018 (MUC16 and CD3 Antibody)	Initiated Phase 1 study in platinum-resistant ovarian cancer	
REGN4659 (CTLA4 Antibody)	Initiated Phase 1 study in advanced NSCLC	
REGN5069 (GFR 3 Antibody)	Initiated Phase 1 study in healthy volunteers	Complete Phase 1 study in healthy volunteers
		Initiate Phase 2 study in osteoarthritis
	Initiated Phase 1 study in multiple myeloma	

REGN5458 (BCMA and CD3 Antibody)

9

Table of Contents

Additional Information on 2018 Developments for Products and Product Candidates

EYLEA (aflibercept) - Ophthalmologic Diseases

In March 2018, we announced that the Phase 3 PANORAMA trial evaluating EYLEA in NPDR met its 24-week primary endpoint. PANORAMA is an ongoing, pivotal, double-masked, randomized two-year trial that enrolled 402 patients and is designed to investigate EYLEA for the improvement of moderately severe and severe NPDR without DME, compared to sham injection. In October 2018, we announced that the Phase 3 PANORAMA trial met its one-year (52-week) primary endpoint and key secondary endpoints. The Company submitted a supplemental Biologics License Application (sBLA) for the treatment of diabetic retinopathy during 2018. 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 (NVG). 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 loss of peripheral vision.

In October 2018, we also announced that the FDA issued a CRL regarding the Chemistry, Manufacturing, and Controls (CMC) PAS for the EYLEA pre-filled syringe. The CRL requested additional information regarding manufacturing and supply processes and the completion of a usability study evaluating a single injection of the EYLEA pre-filled syringe in approximately 30 patients. We are compiling all the requested information and plan to resubmit the PAS in the first half of 2019.

Dupixent (dupilumab) for allergic and inflammatory conditions

In May 2018, we and Sanofi announced that a pivotal Phase 3 trial evaluating Dupixent to treat moderate-to-severe atopic dermatitis in adolescents (ages 12–17) met its primary and key secondary endpoints. In the trial, treatment with Dupixent as monotherapy significantly improved measures of overall disease severity, skin clearing, itching and certain health-related quality of life measures. Patients treated with Dupixent had significant improvement in disease severity at 16 weeks. The primary endpoints were the proportion of patients achieving Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and 75% improvement in Eczema Area and Severity Index (EASI-75, co-primary endpoint outside of the U.S.) at 16 weeks. In the trial, the safety profile of Dupixent was consistent with that seen in adults in previous trials with atopic dermatitis. An sBLA and an MAA for an expanded atopic dermatitis indication in adolescent patients (12–17 years of age) have been submitted.

In October 2018, we and Sanofi announced that both pivotal Phase 3 placebo-controlled trials evaluating Dupixent in adults with inadequately-controlled chronic rhinosinusitis with nasal polyps met all their primary and secondary endpoints. In these trials, Dupixent significantly reduced nasal polyp size, nasal congestion severity, and need for systemic corticosteroids and/or surgery. The rates of adverse events were generally similar across Dupixent and placebo, and no new or unexpected side effects related to Dupixent were observed. An sBLA for CRSwNP has been submitted.

In October 2018, the FDA approved Dupixent as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. Dupixent is currently the only biologic approved for both moderate and severe asthma patients with eosinophilic phenotype and the only biologic approved for oral corticosteroid-dependent asthma, regardless of phenotype.

Praluent (alirocumab) for LDL cholesterol reduction

In March 2018, we and Sanofi announced that the ODYSSEY OUTCOMES trial met its primary endpoint, demonstrating that high-risk patients who added Praluent to maximally-tolerated statins experienced significantly fewer major adverse cardiovascular events compared to those on maximally-tolerated statins alone. For the first time, adding a lipid-lowering therapy to maximally-tolerated statins was associated with reduced death from any cause. A more pronounced effect was observed in patients with baseline LDL-cholesterol (LDL-C) levels at or above 100 mg/dL despite maximally-tolerated statins, who are at high risk of suffering a future event; in this group, Praluent reduced risk of major adverse cardiovascular events by 24% and was associated with a 29% reduced death from any

cause. In this 18,924-patient, long-term trial, the safety profile of Praluent was consistent with previous trials and no new safety issues were observed. Based on the positive results from this trial, an sBLA and an MAA for cardiovascular risk reduction have been submitted.

In September 2018, we and Sanofi announced that the FDA approved an update to the Praluent prescribing information to include clinical information regarding its use in patients with HeFH who require additional lowering of LDL-C along with diet and maximally-tolerated statin therapy and who are undergoing apheresis treatment. The recommended dose of Praluent in patients undergoing LDL apheresis is 150 mg once every two weeks.

Table of Contents

In February 2019, the CHMP adopted a positive opinion for Praluent, recommending a new indication to reduce cardiovascular risk by lowering LDL-C levels in adults with established ASCVD.

Libtayo (cemiplimab) for cancer

The PD-1 immune checkpoint pathway has emerged as a major mechanism by which cancers evade immune destruction. Several drugs blocking either PD-1 or PD-L1 (one of the two ligands that bind PD-1) have been approved. Libtayo is an anti-PD-1 antibody. We are developing Libtayo as a foundation for a diverse and comprehensive immuno-oncology portfolio. Our initial approval strategy is focused on monotherapy in selected indications. Subsequent development activities are expected to include combinations with other anti-cancer agents. Libtayo is also being studied by other companies in combination with their proprietary assets.

As it relates to the Phase 3 program in non-small cell lung cancer, we have recently announced that we are focusing efforts in first-line treatment on combination therapy of cemiplimab with chemotherapy.

On September 28, 2018, the FDA approved Libtayo for the treatment of patients with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo is the first and currently only treatment specifically approved and available for advanced CSCC in the United States.

In August 2018, we and Sanofi entered into a license agreement with Bristol-Myers Squibb Company, E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. Under the agreement, we and Sanofi made an up-front payment of $20.0 million and are obligated to pay royalties of 8.0% on worldwide sales of Libtayo through December 31, 2023, and royalties of 2.5% from January 1, 2024 through December 31, 2026. The up-front payment was shared, and the royalties are shared, equally by us and Sanofi.

Fasinumab for pain due to osteoarthritis

Pain is among the most common reasons people see the doctor and why analgesics, including opioids, are among the most commonly prescribed drugs. Pain is a major cause of work disability and impaired quality of life. Targeting NGF is a potential new way to manage pain without resorting to opiods. NGF expression is elevated in many acute and chronic painful conditions and NGF blockade has demonstrated efficacy in clinical trials. Fasinumab is an antibody to NGF. The fasinumab clinical development program is expected to comprise up to approximately 10,000 patients treated with fasinumab.

We have several ongoing Phase 3 clinical studies of fasinumab in patients with pain due to osteoarthritis of the knee or hip. In April 2018, an independent DMC monitoring the ongoing safety and efficacy of the fasinumab clinical trials recommended that the higher dose-regimens be discontinued based on the risk benefit assessment and that the program may continue with the lower dose-regimens of fasinumab. The ongoing osteoarthritis trials have been modified accordingly. Since the Phase 3 clinical study in chronic low back pain in patients with concomitant osteoarthritis was using only higher doses, we discontinued dosing patients in this study.

In August 2018, we and Teva announced positive top-line results from our Phase 3 study of fasinumab in patients with chronic pain from osteoarthritis of the knee or hip. At the week 16 primary efficacy analysis, the study met both co-primary endpoints and all key secondary endpoints. Fasinumab-treated patients experienced significantly less pain and significantly improved functional ability from baseline compared to placebo. Interim safety data indicate that fasinumab was generally well tolerated, with similar adverse events as those observed in previous fasinumab trials. After the primary efficacy assessment at week 16, patients continue on therapy for an additional 36 weeks, followed by a subsequent 20-week off study drug follow-up period for further safety assessment.

Other Programs

Our preclinical research programs include the areas of oncology and 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 2017, we and BARDA entered into an agreement to discover, research, develop, and manufacture a portfolio of antibodies targeting up to 10 pathogens, starting with Influenza virus, that pose significant risk to public health. The emerging pathogens treatment portfolio will be pursued using an Other Transaction Agreement (OTA), which provides a funding and collaboration vehicle for HHS to promote innovation in technology for advanced research and development. Under the OTA, which has a term of 10 years, HHS will fund 80% of our costs for research,

development, and manufacturing activities for antibodies that are selected to move forward.

Table of Contents

Research and Development Technologies

Many proteins that play an important role in biology and disease are secreted by cells or located on the cell surface. Moreover, cells communicate through secreted factors and surface molecules. Our scientists have developed two different technologies to make protein therapeutics that potently and specifically block, activate, or inhibit the action of specific cell surface or secreted molecules. The first technology fuses receptor components to the constant region of an antibody molecule to make a class of drugs we call "Traps". EYLEA, ZALTRAP, and ARCALYST are drugs generated using our Trap technology. VelociSuite is our second technology platform. It is used for discovering, developing, and producing fully human antibodies that can address both secreted and cell-surface targets.

VelociSuite. VelociSuite consists of VelocImmune, VelociGene, VelociMouse®, VelociMab, Veloci-Bi™, and other related technologies. The VelocImmune mouse platform is utilized to produce fully human 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 efficiently to generate fully human antibodies to targets of therapeutic interest. VelocImmune and our entire VelociSuite offer the potential to increase the speed and efficiency through which human 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 antibodies.

We have utilized our VelociSuite technologies to develop a class of potential drug candidates, known as bi-specific antibodies. Veloci-Bi allows for the generation of full-length bi-specific antibodies similar to native antibodies that are amenable to production by standard antibody manufacturing techniques, and are likely to have favorable antibody-like pharmacokinetic properties. 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, REGN1979, targets CD20 and CD3. We are exploring additional indications and applications for our bi-specific technologies, such as bi-specific antibodies to mucin 16 (MUC16) and B-cell maturation antigen (BCMA), as well as a new class of co-stimulatory bi-specifics, the first two of which are expected to enter clinical development in 2019.

Regeneron Genetics Center®. Regeneron Genetics Center (RGC), a wholly owned subsidiary of Regeneron Pharmaceuticals, Inc., 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 addition, RGC has expanded on its foundational population-based collaboration with Geisinger with a growing number of other organizations worldwide.

In addition, RGC has formed a consortium to fund the generation of genetic exome sequence data from 500,000 volunteer participants who make up the UK Biobank health resource. The current members of the consortium consist of AbbVie Inc., Alnylam Pharmaceuticals Inc., AstraZeneca PLC, Biogen Inc., Pfizer Inc., Millennium Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Unlimited), and Bristol-Myers Squibb. The consortium members have each committed up to $10.0

Table of Contents

million in funding for Regeneron to sequence the UK Biobank's samples, which will be performed at the RGC facility. Consortium members will have a limited period of exclusive access to the sequencing data before the data will be made available to other health researchers by UK Biobank.

Researchers from the RGC discovered a potential new therapeutic target to reduce the risk of chronic liver disease and progression to more advanced stages of disease, such as nonalcoholic steatohepatitis (NASH), by analyzing extensive genetic sequencing data linked with electronic health records. In March 2018, we announced a publication describing this discovery in the New England Journal of Medicine, which identified for the first time a variant in the HSD17B13 gene that is associated with reduced risk of, or protection from, various chronic liver diseases for which there are currently no approved therapeutics. We are collaborating with Alnylam to discover RNA interference (RNAi) therapeutics for NASH and potentially other related diseases.

Collaboration Agreements

Collaborations with Sanofi

Antibodies. We are collaborating with Sanofi on the global development and commercialization of various antibodies and antibody product candidates (Dupixent, Praluent, Kevzara, and REGN3500) (the Antibody Collaboration). Under the terms of the Antibody License and Collaboration Agreement (LCA), 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. All other agreed-upon development costs incurred by both companies are funded 100% by Sanofi. 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.

Effective January 7, 2018, we and Sanofi entered into a letter agreement (Letter Agreement) amending the LCA in connection with, among other matters, the allocation of additional funds to certain proposed activities relating to dupilumab and REGN3500 (collectively, the Dupilumab/REGN3500 Eligible Investments). Pursuant to the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to the Dupilumab/REGN3500 Eligible Investments for the quarterly periods commencing on January 1, 2018 and ending on September 30, 2020 by selling up to an aggregate of 600,000 shares (of which 589,234 currently remains available) of our Common Stock directly or indirectly owned by Sanofi. Refer to the "Immuno-Oncology" section below for further details regarding the Letter Agreement.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-promote such products on a country-by-country basis. We have exercised our option to co-promote Dupixent, Praluent, and Kevzara in the United States. We have thus far not exercised any of our options to co-promote these antibodies outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi 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 and loss sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales of antibodies (subject to this agreement) outside the United States exceed $1.0 billion on a rolling twelve-month basis.

Immuno-Oncology. In July 2015, we 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 Amended and Restated Immuno-oncology Discovery and Development Agreement (Amended IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the execution of the original Immuno-oncology Discovery and Development Agreement in 2015 (2015 IO Discovery Agreement), which has been replaced by the Amended IO Discovery Agreement (as discussed below), Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the 2015 IO Discovery Agreement, we were to 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, and Sanofi was to reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits. The original term of the 2015 IO Discovery Agreement was to continue

through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget was 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.

Effective December 31, 2018, the Company and Sanofi entered into the Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company (IO Development Activities) under the 2015 IO Discovery Agreement to developing therapeutic bi-specific antibodies targeting (i) BCMA and CD3 (the BCMAxCD3 Program) and (ii) MUC16 and CD3 (the MUC16xCD3 Program) through clinical proof of concept. The Amended IO Discovery Agreement provided for Sanofi's payment of $461.9 million to the Company as consideration for (x) the termination of the 2015 IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the

Table of Contents

MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the 2015 IO Discovery Agreement during the fourth quarter of 2018.

Under the terms of the Amended IO Discovery Agreement, the Company is required to conduct development activities with respect to (i) the BCMAxCD3 Program through the earlier of clinical proof-of-concept or the expenditure of $70.0 million (the BCMAxCD3 Program Costs Cap) and (ii) the MUC16xCD3 Program through the earlier of clinical proof of concept or the expenditure of $50.0 million (the MUC16xCD3 Program Costs Cap); provided that under certain circumstances, Sanofi will have the option to increase the MUC16xCD3 Program Costs Cap to $70.0 million by making a payment to the Company in the amount of $20.0 million.

Pursuant to the Amended IO Discovery Agreement, we are primarily responsible for conducting the IO Development Activities , other than certain clinical trials that may be funded separately by Sanofi, including antibody development, preclinical activities, toxicology studies, manufacture of clinical supplies, filing of Investigational New Drug Applications (INDs), and clinical development through proof-of-concept. We are obligated to 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. As the scope of the IO Development Activities has been limited, the exclusivity obligations of the parties under the Amended IO Discovery Agreement have been narrowed.

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when clinical proof-of-concept is established, the applicable Program Costs Cap is reached, or in certain other limited circumstances, Sanofi will have the option to license rights to the product candidate and other antibodies targeting the same targets for, with regard to BCMAxCD3, immuno-oncology indications, and with regard to MUC16xCD3, all indications, pursuant to the IO License and Collaboration Agreement, as amended. 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 receive a royalty on sales. Pursuant to the Amended IO Discovery Agreement, the parties agreed that (i) if Sanofi exercises its option with respect to a BCMAxCD3 Program antibody, Sanofi will lead the development and commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) the Company will lead the development of such MUC16xCD3 Program antibody and commercialization of such MUC16xCD3 Program antibody within the United States and (y) Sanofi will lead the commercialization of such MUC16xCD3 Program antibody outside of the United States.

The Amended IO Discovery Agreement provides that Regeneron retains exclusive rights to all other immuno-oncology programs that were part of the 2015 IO Discovery Agreement, provided that Sanofi will receive a royalty on global sales of two product candidates currently in clinical development, REGN3767 and REGN4659. The Amended IO Discovery Agreement will terminate as of the earlier of (a) Sanofi having elected to exercise or not exercise its options with respect to the BCMAxCD3 Program and the MUC16xCD3 Program in accordance with the terms of the Amended IO Discovery Agreement and (b) December 31, 2022.

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 BCMAxCD3 Program antibody or MUC16xCD3 Program antibody thereunder, it will co-develop these drug candidates with us through product approval under the terms of the IO License and Collaboration Agreement. Sanofi will fund development costs up front for a BCMAxCD3 Program antibody and we will reimburse half of the total development costs for such antibody 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 a MUC16xCD3 Program antibody. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties are also co-developing Libtayo (cemiplimab), an antibody targeting PD-1. We have principal control over the development of Libtayo, and the parties share equally, on an ongoing basis, development expenses for Libtayo. Pursuant to the January 7, 2018 Letter

Agreement with Sanofi, we and Sanofi agreed to increase the Libtayo development budget to a total of $1.640 billion as of the effective date of the Letter Agreement, $990.0 million over the budget originally set forth in the IO License and Collaboration Agreement (with further changes to the Libtayo development budget possible by agreement of the parties). Under the Letter Agreement, we have also agreed to allow Sanofi to satisfy in whole or in part its funding obligation with respect to Libtayo development costs for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to an aggregate of 800,000 shares (of which 584,613 currently remains available) of our Common Stock directly or indirectly owned by Sanofi.

If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or, as noted above, Dupilumab/REGN3500 Eligible Investments, we may

Table of Contents

elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions.

With regard to Libtayo, we 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. Sanofi has exercised its option to co-promote Libtayo in the United States. We will be entitled to a milestone payment of $375.0 million in the event that global sales of certain licensed products targeting PD-1 (including Libtayo), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with any of such licensed products 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, 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.

Collaboration with Mitsubishi Tanabe Pharma

Fasinumab. 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. As of December 31, 2018, we had earned an aggregate of $135.0 million in development milestones and other contingent payments from MTPC, and are entitled to receive up to an aggregate of $80.0 million in additional 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, except in the MTPC territories (as described above). In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment in 2016. We lead global development activities, and the parties will share equally, on an ongoing basis, development costs under a global development plan. As of December 31, 2018, we had earned an aggregate of $120.0 million of development milestones from Teva, and we are entitled to receive up to an aggregate of $340.0 million in additional 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 bluebird

In August 2018, we entered into a collaboration agreement with bluebird bio, Inc. to research, develop, and commercialize novel immune cell therapies for cancer. Under the terms of the agreement, the parties have jointly selected six initial targets and will equally share the costs of research and development, which will be led by bluebird, up to IND acceptance. Additional targets

Table of Contents

may be selected over the five-year research collaboration term. With respect to certain targets, upon the acceptance of an IND, we will have the option to co-develop and co-commercialize product candidates directed to such target; if we exercise this option, the parties will share equally in the costs of development and commercialization, and will share in any profits or losses therefrom. If we do not exercise our option or we do not have an option to a target, we are entitled to receive milestone payments and royalties on any future sales of products developed and commercialized by bluebird under the terms of the agreement.

In connection with the execution of the collaboration agreement, we also agreed to purchase 420,000 shares of bluebird common stock for $100.0 million. The purchase was completed in the third quarter of 2018. As part of the agreement, $37.0 million, the amount paid in excess of the fair market value of the shares purchased based upon bluebird's closing price on August 3, 2018 of $150.00 per share, will be credited against our funding obligation for collaboration research.

Manufacturing

We currently manufacture bulk drug materials at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland. The Rensselaer facility consists of approximately 565,000 square feet of owned research, manufacturing, office, and warehouse space. We currently have approximately 100,000 liters of cell culture capacity at our Rensselaer facility, and are approved by the FDA and other regulatory agencies to manufacture our marketed products.

We also own an approximately 445,000 square foot facility in Limerick, Ireland, which we acquired and subsequently renovated to accommodate and support our growth and expand our manufacturing capacity. The facility has received certain manufacturing approvals by regulatory agencies, including the FDA, and is in the process of further validation, as required by regulatory authorities, for the manufacture of our bulk drug products.

Certain bulk drug materials are also manufactured by our collaborators, and certain raw materials or 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 our collaborators or 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.

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 our marketed products, 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 approximately 700 field-based employees in the United States.

Table of Contents

Customers

We sell EYLEA and Libtayo 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 and Libtayo, 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 two customers (Besse Medical, a subsidiary of AmerisourceBergen Corporation, and McKesson Corporation) that each accounted for more than 10% of total gross product revenue for the year ended December 31, 2018. On a combined basis, our product sales to these customers accounted for approximately 92% of our gross product revenue for the year ended December 31, 2018. 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 Dupixent, Praluent, and Kevzara, respectively.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies. 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 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.

The tables below provide an overview of the competitive landscape for our key marketed products in their currently approved indications, focusing primarily on competing approved products and product candidates that have advanced beyond Phase 1 clinical development. The tables below are not exhaustive. For additional information regarding the substantial competition these marketed products face, see also Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - The commercial success of our products and product candidates is subject to strong competition."

EYLEA

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Lucentis® (ranibizumab)	Approved	Novartis AG and Genentech/Roche	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	Genentech/Roche	Wet AMD, DME, and macular edema following RVO	Worldwide
Ozurdex® (dexamethasone intravitreal implant)	Approved	Allergan, PLC	DME, RVO	Worldwide
Iluvien® (fluocinolone acetonide intravitreal implant)	Approved	Alimera Sciences, Inc.	DME	United States, EU
Conbercept			Wet AMD	China

Approved in China for wet AMD In development in the United States and the EU (two non-inferiority Phase 3 trials comparing dosing regimens of conbercept to EYLEA initiated in 2018)	Chengdu Kanghong Pharmaceutical Group Co., Ltd.

Table of Contents

EYLEA (continued)

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Brolucizumab (RTH258), a single chain antibody fragment directed against VEGF-A	In development (two non-inferiority Phase 3 trials comparing RTH258 and EYLEA met their primary endpoint in June 2017)	Novartis	Wet AMD and related conditions	—
Abicipar pegol (anti-VEGF-A-DARPin®)	In development (two non-inferiority Phase 3 trials comparing dosing regimens of abicipar pegol and Lucentis reported to have met their primary endpoints in July 2018)	Allergan	Wet AMD and related conditions	—
Faricimab (RG7716), a bi-specific antibody targeting anti-VEGF and Ang2	In development (two non-inferiority Phase 3 trials comparing dosing regimens of faricimab and EYLEA in DME reported to have been initiated in September 2018)	Genentech/Roche	Wet AMD, DME	—
Ranibizumab port delivery system	In development (non-inferiority Phase 3 trial comparing ranibizumab administered via the Port Delivery System and monthly intravitreal injections of Lucentis in wet AMD reported to have been initiated in September 2018)	Genentech/Roche	Wet AMD and related conditions	—
DE-122, an anti-endoglin antibody in development for use in combination with EYLEA or Lucentis	In development (Phase 2)	Santen Pharmaceuticals Co. Ltd./ TRACON Pharmaceuticals, Inc.	Wet AMD and related conditions	—
GB-102, an intravitreally administered depot formulation of the small molecule tyrosine kinase inhibitor, sunitinib	In development (Phase 2)	Graybug Vision, Inc.	Wet AMD and related conditions	—
OPT-302, a VEGFR-3 large molecule trap in development for use in combination with EYLEA or Lucentis	In development (Phase 2b)	Opthea Limited	Wet AMD and related conditions	—
PAN-90806, a topically administered tyrosine kinase inhibitor	In development (Phase 1/2)	PanOptica, Inc.	Wet AMD	—
KSI-301, an anti-VEGF biologic therapy that is conjugated to a phosphorylcholine-based biopolymer to extend its half-life	In development (Phase 1b)	Kodiak Sciences Inc.	Wet AMD, DME, and RVO	—
RGX-314, a gene therapy	In development (Phase 1)	REGENXBIO Inc.	Wet AMD	—

18

Table of Contents

EYLEA (continued)

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
M710, a biosimilar to EYLEA	In development (Phase 3)	Momenta Pharmaceuticals, Inc. (in partnership with Mylan N.V.)	Wet AMD and related conditions	—
PF582, a biosimilar to Lucentis	In development (Phase 1/2 completed in August 2016)	Pfenex Inc.	Wet AMD and related conditions	—
FYB201, a biosimilar to Lucentis	In development (Phase 3 trial of FYB201 and Lucentis completed in December 2018)	Formycon AG (in collaboration with Bioeq GmbH)	Wet AMD and related conditions	—
SB11, a biosimilar to Lucentis	In development (Phase 3)	Samsung Bioepis Co., Ltd.	Wet AMD and related conditions	—
Razumab, a biosimilar to Lucentis	Approved in India for wet AMD and related conditions	Intas Phamaceuticals Limited	Wet AMD and related conditions	India

Dupixent

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Eucrisa® (crisaborole)	Approved	Pfizer	Mild-to-moderate atopic dermatitis	United States
Xolair® (omalizumab)	Approved	Roche/Novartis	Asthma	Worldwide
Nucala® (mepolizumab)	Approved	GlaxoSmithKline (GSK)	Asthma	Worldwide
Cinqair® (reslizumab)	Approved	Teva	Asthma	Worldwide
Fasenra® (benralizumab)	Approved	AstraZeneca	Asthma	United States, EU
Tralokinumab, an anti-IL-13 antibody	In development (Phase 3)	AstraZeneca/ LEO Pharma Inc.	Atopic dermatitis	—
Baricitinib, an orally administered JAK inhibitor	In development (recently reported to have met the primary endpoints of two atopic dermatitis Phase 3 studies)	Eli Lilly and Company/Incyte Corporation	Atopic dermatitis	—
Abrocitinib (PF-04965842), an orally administered JAK inhibitor	In development (Phase 3)	Pfizer	Atopic dermatitis	—
Upadacitinib, an orally administered JAK inhibitor	In development (Phase 3)	AbbVie	Atopic dermatitis	—
Fevipiprant, an orally administered CRTH2 antagonist	In development (Phase 3)	Novartis	Asthma	—
Tezepelumab, an anti-TSLP antibody	In development (Phase 3 for asthma and Phase 2 for atopic	Amgen Inc./AstraZeneca	Asthma and atopic dermatitis	—

	dermatitis)			
Etiokimab (ANB-020), an anti-IL-33 antibody	In development (Phase 2)	AnaptysBio, Inc.	Asthma and atopic dermatitis	—

Table of Contents

Dupixent (continued)

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Lebrikizumab, an anti-IL-13 antibody	In development (Phase 2b)	Dermira, Inc./Roche	Atopic dermatitis	—
Nemolizumab, an anti-IL-31R antibody	In development (Phase 2b reported to have been completed; Phase 3 initiation expected in 2019)	Galderma S.A.	Atopic dermatitis	—
GSK3772847, an anti-ST2 antibody	In development (Phase 2 for asthma and Phase 1 for atopic dermatitis)	GSK	Asthma and atopic dermatitis	—
RG6149, an anti-ST2 antibody	In development (Phase 2)	Roche	Asthma and atopic dermatitis	—
CSJ117, an inhaled antibody fragment against thymic stromal lymphopoietin	In development (Phase 1)	Novartis	Asthma	—
GBR-830, an anti-OX40 antibody	In development (Phase 2b)	Glenmark Pharmaceuticals Ltd.	Atopic dermatitis	—
KHK4083, an anti-OX40 antibody	In development (Phase 2)	Kyowa Hakko Kirin Co., Ltd.	Atopic dermatitis	—
ASN002, an orally administered dual JAK/SYK inhibitor	In development (Phase 2b)	Asana BioSciences, LLC	Atopic dermatitis	—
ZPL389, an orally administered histamine H4 receptor agonist	In development (Phase 2)	Novartis	Atopic dermatitis	—
Bermekimab, an anti-IL-1alpha antibody	In development (Phase 2 completed)	XBiotech Inc.	Atopic dermatitis	—
MOR-106, an anti-IL-17C antibody	In development (Phase 2)	Novartis/ MorphoSys, AG	Atopic dermatitis	—
KPL-716, an antibody against the oncostatin M receptor beta	In development (Phase 1 reported to have been completed)	Kiniksa Pharmaceuticals, Ltd.	Atopic dermatitis	—
PRS-060, an inhaled anticalin targeting IL-4R	In development (Phase 1)	AstraZeneca/ Pieris Pharmaceuticals, Inc.	Asthma	—
ASLAN004, an antibody against the IL-13R alpha-1 subunit	In development (Phase 1)	ASLAN Pharmaceuticals	Atopic dermatitis	—

Table of Contents

Praluent

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Repatha® (evolocumab)	Approved	Amgen	(1) Reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, (2) primary hyperlipidemia, and (3) HoFH	Worldwide
Inclisiran (ALN-PCSsc)	In development (Phase 3)	Alnylam Pharmaceuticals (in collaboration with The Medicines Company)	RNAi molecule against PCSK9 (injectable, small molecule)	—
ETC-1002 (bempedoic acid)	In development (Phase 3)	Esperion Therapeutics, Inc.	ACL-inhibitor (oral, small molecule)	—

Kevzara

Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Actemra® (tocilizumab)	Approved	Genentech/Roche/ Chugai Pharmaceutical Co., Ltd.	Rheumatoid arthritis	Worldwide
Orencia® (abatacept)	Approved	Bristol-Myers Squibb	Rheumatoid arthritis	Worldwide
Xeljanz® (tofacitinib)	Approved	Pfizer	Rheumatoid arthritis	Worldwide
Olumiant® (baricitinib)	Approved	Eli Lilly/Incyte	Rheumatoid arthritis	United States, EU
Olokizumab, an anti-IL-6 antibody	In development (Phase 3)	R-Pharm	Rheumatoid arthritis	—
Upadacitinib, an orally administered JAK inhibitor	In development (Submitted for regulatory approval)	AbbVie	Rheumatoid arthritis	—
Filgotinib, an orally administered JAK inhibitor	In development (Phase 3)	Gilead Sciences, Inc./ Galapagos NV	Rheumatoid arthritis	—
Peficitinib, an orally administered JAK inhibitor	In development (Phase 3)	Astellas Pharma Inc.	Rheumatoid arthritis	—
BCD-089, an anti-IL-6R antibody	In development (Phase 2)	BIOCAD	Rheumatoid arthritis	—
LusiNEX, a biosimilar to Actemra	In development (Phase 1 trials reported to have been completed)	Mycenax Biotech Inc.	Rheumatoid arthritis	—
BAT1806, a biosimilar to Actemra	In development (Phase 1)	Bio-Thera Solutions Ltd.	Rheumatoid arthritis	—

Table of Contents

Libtayo Competitor Product/Product Candidate	Commercial or Development Status	Competitor	Indication	Territory
Opdivo® (nivolumab)	Approved	Bristol-Myers Squibb	Various Cancers	Worldwide
Keytruda® (pembrolizumab)	Approved	Merck & Co., Inc.	Various Cancers	Worldwide
Bavencio® (avelumab)	Approved	Pfizer/Merck	Various Cancers	Worldwide
Tecentriq® (atezolizumab)	Approved	Roche	Various Cancers	Worldwide
Imfinzi® (durvalumab)	Approved	AstraZeneca	Various Cancers	Worldwide
Spartalizumab (PDR001), an antibody against PD-1	In development (Phase 3)	Novartis	Various Cancers	—
Tislelizumab (BGB-A317), an antibody against PD-1	In development (Phase 3)	Celgene Corporation/ BeiGene Ltd.	Various Cancers	—
AGEN2034, an antibody against PD-1	In development (Phase 1/2)	Agenus Inc.	Various Cancers	—
Dostarlimab (TSR-042), an antibody against PD-1	In development (Phase 2/3)	GSK/ AnaptysBio	Various Cancers	—
INCMGA0012, an antibody against PD-1	In development (Phase 2)	Incyte/ MacroGenics, Inc.	Various Cancers	—
JNJ-63723283, an antibody against PD-1	In development (Phase 1/2)	Johnson & Johnson	Various Cancers	—
PF-06801591, an antibody against PD-1	In development (Phase 1)	Pfizer	Various Cancers	—

Antibodies in Development. Our clinical candidates in development are all fully human 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 have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

The following table provides an overview of the competitive landscape for our antibody programs that are in late-stage clinical development, focusing primarily on product candidates that have advanced beyond Phase 1 clinical development:

Regeneron Antibody Program	Competitor	Competitor Product/Product Candidate	Commercial or Development Status	Target
Fasinumab (Phase 3) Target: NGF	Pfizer/Eli Lilly	Tanezumab	In development (Phase 3)	Antibody against NGF
Evinacumab (Phase 3) Target: ANGPTL3	Ionis Pharmaceuticals, Inc./Akcea Therapeutics, Inc.	AKCEA-ANGPTL3-LRx	In development (Phase 2)	Ligand conjugated antisense drug against ANGPTL3
Evinacumab		ARO-ANG3		RNAi against ANGPTL3

Arrowhead Pharmaceuticals, Inc.	In development (Phase 1)

The table above is not exhaustive and focuses 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 additional information regarding our antibody programs and the substantial competition they face, see Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - The commercial success of our products and product candidates is subject to strong competition."

Table of Contents

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

We rely on a combination of intellectual property laws, including patent, trademark, copyright, trade secret, and domain name protection laws, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights.

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 Note 17 to our Consolidated Financial Statements). 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 thousands 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 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.

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.

Table of Contents

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, 2020
		EP	1183353	Supplementary Protection Certificate	(May 23, 2025)**
		EP	2364691	Formulation	June 14, 2027
		EP	1544299	Methods of Treatment	May 23, 2020
Dupixent***	dupilumab	US	7,608,693	Composition of Matter	October 2, 2027
		US	8,945,559	Formulation	October 17, 2032
		US	8,075,887	Methods of Treatment	April 17, 2028
		US	8,337,839	Methods of Treatment	October 2, 2027
		US	9,290,574	Methods of Treatment	July 10, 2034
		US	9,574,004	Methods of Treatment	December 22, 2033
		EP	2356151	Composition of Matter	October 27, 2029
		EP	2356151	Supplementary Protection Certificate	(September 28, 2032)**
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
		US	9,550,837	Methods of Treatment	December 15, 2029
		US	9,724,411	Methods of Treatment	January 15, 2031
		EP	2358756	Composition of Matter	December 15, 2029
		EP	2358756	Supplementary Protection Certificate	(September 25, 2030)**
Kevzara	sarilumab	US	7,582,298	Composition of Matter	January 4, 2028
		US	9,173,880	Formulation	December 6, 2031
		US	8,080,248	Methods of Treatment	June 1, 2027
		EP	2041177	Composition of Matter	June 1, 2027
		EP	2041177	Supplementary Protection Certificate	(June 1, 2032)**
		EP	2766039	Methods of Treatment	October 10, 2032
Libtayo	cemiplimab	US	9,987,500	Composition of Matter	September 18, 2035

* 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 (SPCs) are pending and/or have been granted in various European countries, extending the original patent terms in those countries, where granted, to the dates indicated in parentheses.

*** See Note 17 to our Consolidated Financial Statements for information regarding the patent infringement proceedings relating to EYLEA, Dupixent, and Praluent.

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. These include a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. to obtain a license under

24

Table of Contents

certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. Under the agreement, we and Sanofi pay royalties of 8.0% on worldwide sales of Libtayo through December 31, 2023, and royalties of 2.5% from January 1, 2024 through December 31, 2026. The royalties are shared equally by us and Sanofi.

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.

We seek to file and maintain trademarks around the world based on commercial activities in most jurisdictions where we have, or desire to have, a business presence for a particular product or service. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

Defense and enforcement of our intellectual property rights is expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights"; and Note 17 to our Consolidated Financial Statements).

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. A summary of the primary areas of government regulation that are relevant to our business is provided below. For a description of material regulatory risks we face, also refer to Part I, Item 1A. "Risk Factors."

Preclinical Requirements

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. Certain preclinical trials must comply with the FDA's Good Laboratory Practice requirements (GLPs) and the U.S. Department of Agriculture's Animal Welfare Act. 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. In other countries, the data are reviewed by regulatory authorities as part of clinical trial applications. The FDA or other regulatory authorities may ask for additional data in order to begin a clinical study.

Product Approval

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. The structure and substance of the FDA and foreign pharmaceutical regulatory practices may evolve over time. The ultimate outcome and impact of such developments cannot be predicted.

Typically, clinical testing involves a three-phase process. In Phase 1, trials are usually conducted with a small number of healthy volunteers 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, larger 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. If concerns arise about the safety of the product candidate, the FDA or other regulatory authorities can stop clinical trials by placing them on a "clinical hold" pending receipt of additional data, which can result in a delay or termination of a clinical development program. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application (BLA) for evaluation to determine whether the product

Table of Contents

candidate may be approved for commercial sale under the Public Health Service Act. Under the Prescription Drug User Fee Act, we typically must pay fees to the FDA for review of any BLA, which can exceed $2 million per filing. 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, among other things, the manufacture, shipment, and storage of the product. The FDA also can audit the sponsor of the BLA to determine if the clinical studies were conducted in compliance with current Good Clinical Practice, or cGCP, requirements.

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 different or additional testing, and the time required to obtain such approval may differ from that required for FDA approval. Approval by a regulatory authority in one jurisdiction does not guarantee approval by comparable regulatory authorities in other jurisdictions.

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 developing and commercializing 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.

For additional information regarding U.S. and foreign regulatory approval processes and requirements, see Part I, Item 1A. "Risk Factors - 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."

Post-Approval Regulation

The FDA and comparable regulatory authorities in other jurisdictions may also require us to conduct additional clinical trials or to make certain changes related to a product after granting approval of the product. 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.

Following approval, the FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA regulations and standards thereunder. The FDA's review of promotional activities includes, but is not limited to, 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 and promotion laws and regulations. See Part I, Item 1A. "Risk Factors - Regulatory and Litigation Risks - 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."

Adverse-event reporting and submission of periodic reports are required following marketing approval. The FDA requires BLA holders to employ a system for obtaining and reviewing safety information, adverse events, and product complaints associated with each drug and submit safety reports to the FDA, with expedited reporting timelines in certain situations. Based on new safety information after approval, the FDA can, among other things, mandate product labeling changes, require new post-marketing studies, impose or modify a risk evaluation and mitigation strategy for the product, or suspend or withdraw approval of the product. We may be subject to audits by the FDA and other regulatory authorities to ensure that we are complying with the applicable requirements.

In addition, we and our third-party suppliers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable regulatory authorities 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 regulatory authorities and acceptance of the change by the FDA or such comparable foreign regulatory authorities prior to release of product(s). FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and our third-party suppliers. Prescription drug manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and

Table of Contents

properly handle suspect and illegitimate products. We may also be subject to state regulations related to the manufacturing and distribution of our products.

Failure to comply with these laws and regulations may lead the FDA and comparable regulatory authorities in other jurisdictions to take regulatory action, which could include ordering the suspension of manufacturing or withdrawing FDA approval of a product.

Pricing and Reimbursement

Sales in the United States of our marketed products 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 our marketed products in other countries are dependent, in large part, on coverage and reimbursement mechanisms and programs administered by health authorities in those countries. See Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - Sales of our marketed products 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."

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program, several state Medicaid supplemental rebate programs, and other governmental pricing programs. We also have obligations to report the average sales price for certain of our drugs to the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Medicaid rebates are based on pricing data reported by us on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the Medicaid and Medicare programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. The amount of the rebate is adjusted upward if average manufacture price increases more than inflation (measured by reference to the Consumer Price Index - Urban). If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due, which revisions could affect our rebate liability for prior quarters. The federal Patient Protection and Affordable Care Act (PPACA) made significant changes to the Medicaid Drug Rebate program, and CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the PPACA.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners are provided in connection with certain durable medical equipment or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price of the drugs. Manufacturers, including us, are required to report average sales price information to CMS on a quarterly basis. The manufacturer-submitted information is used by CMS to calculate Medicare payment rates.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing or other information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program (340B program) in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health

Resources and Services Administration, or HRSA, requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. Covered entities include hospitals that serve a disproportionate share of financially needy patients, community health clinics, and other entities that receive certain types of grants under the Public Health Service Act. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement.

Table of Contents

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. Any charge by HRSA that we have violated the requirements of the regulation could result in civil monetary penalties. HRSA also has announced that it will begin to implement a ceiling price reporting requirement related to the 340B program during the first quarter of 2019. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the U.S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. FSS participation is required for our products to be purchased by the VA, Department of Defense (DoD), Coast Guard, and Public Health Service (PHS). Prices for innovator drugs purchased by the VA, DoD, Coast Guard, and PHS are subject to a cap (known as the Federal Ceiling Price) equal to 76% of the annual non-federal average manufacturer price (non-FAMP) minus an additional discount. The additional discount applies if the current year Q3 non-FAMP is greater than the prior year Q3 non-FAMP by more than the allowable inflation rate (measured by reference to the Consumer Price Index - Urban). We also participate in the Tricare Retail Pharmacy Program, under which we pay quarterly rebates to DoD for prescriptions of our innovator drugs dispensed to Tricare beneficiaries through Tricare Retail network pharmacies. The governing statute provides for civil monetary penalties for failure to provide information timely or for knowing submission of false information to the government.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and, subject to detailed program rules and government oversight, each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, for 2019, manufacturers, including us, are required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design.

Private payor healthcare and insurance providers, health maintenance organizations, and pharmacy benefit managers in the United States are adopting more aggressive utilization management techniques and are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment/coinsurance. As a consequence, these payers may not cover or adequately reimburse for use of our products or may do so at levels that disadvantage them relative to competitive products.

Outside the United States, within the EU, our products are paid for by a variety of payors, with governments being the primary source of payment. Government health authorities in the EU determine or influence reimbursement of products, and set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of our products. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries or prices of competitive products and using those reference prices to set a price). Budgetary pressures in many EU countries are continuing to cause governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates, and expanded generic substitution and patient cost-sharing.

Other 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. 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. See Part I, Item 1A. "Risk Factors - Regulatory and Litigation Risks - 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."

We 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. See Part I, Item 1A. "Risk Factors - Regulatory and Litigation Risks - 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."

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of personal information. In addition, most health care providers, including research institutions from which we or our collaborators obtain patient health information, are

Table of Contents

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. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Outside the United States, our clinical trial programs and research collaborations may implicate international data protection laws, including the General Data Protection Regulation (GDPR) in the EU. The GDPR became effective on May 25, 2018, increasing our responsibility and liability in relation to the processing of personal data of EU subjects. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EU, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU. Guidance on implementation and compliance practices are often updated or otherwise revised. See Part I, Item 1A. "Risk Factors - Regulatory and Litigation Risks - 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."

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

Business Segments

We manage our business as one segment which includes all activities related to the discovery, development, and commercialization of 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, 2018, we had approximately 7,400 full-time employees. 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. 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.

The information contained on our websites and social media channels is not included as a part of, or incorporated by reference into, this report.

Table of Contents

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 Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products

We are substantially dependent on the success of EYLEA.

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, 2018 and 2017, EYLEA net sales in the United States represented 61% and 63% 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.

If we or our collaborators are unable to continue to successfully commercialize our products, our business, prospects, operating results, and financial condition will be materially harmed.

We expect that the continued commercial success of our marketed products (in particular, EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) will depend on many factors, including the following (as applicable):

- effectiveness of the commercial strategy in and outside the United States for the marketing of our products, including pricing strategy;
- sufficient coverage of, and reimbursement for, our marketed products by third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions, as well as payer restrictions on eligible patient populations and the reimbursement process, both in the United States and abroad;
- our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development; and, in the case of EYLEA, 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;
- maintaining and successfully monitoring commercial manufacturing arrangements for our marketed products with third parties who perform fill/finish or other steps in the manufacture of such products 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 our marketed products;
- the outcome of the pending patent infringement proceedings relating to EYLEA, Dupixent, and Praluent (described further in Note 17 to our Consolidated Financial Statements included in this report), and other risks relating to our marketed products 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 results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and studies of other products that could implicate an entire class of products or are perceived to do so; and
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescribing practices.

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

30

Table of Contents

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or our collaborators commercialize. If we or our collaborators fail to maintain regulatory compliance for any of such products, the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or they commercialize (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) for the products' currently approved indications in the United States, EU, and other countries where such products are approved. If we or our collaborators fail to maintain regulatory compliance for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies, or 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"), the applicable 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 - Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring 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 our marketed products could materially harm our business, prospects, operating results, and financial condition.

Serious complications or serious, unexpected side effects in connection with the use of our marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) 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.

Sales of our marketed products 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.

Sales of our marketed products (such as EYLEA, Dupixent, Praluent, Kevzara, and Libtayo) in the United States 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 our marketed products in other countries are dependent, in large part, on similar reimbursement mechanisms and programs in those countries.

Our future revenues and profitability will be adversely affected in a material manner if such third-party payers do not adequately defray or reimburse the cost of our marketed products to patients. If these entities do not provide coverage and reimbursement with respect to our marketed products or provide an insufficient level of coverage and reimbursement, such 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 marketed 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 the CMS. There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage, as discussed further below) of our current and future marketed products, which may have a material adverse effect on our business.

Table of Contents

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. Some states are also considering legislation that would control the prices and reimbursement of prescription 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 prescription 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 measures in the future that will impose additional constraints on prices and reimbursements for our marketed products.

Further, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. At the federal level, the current administration's budget proposal for fiscal year 2019 contains drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B (such as EYLEA), to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. The Department of Health and Human Services has been soliciting feedback on some of these measures and may implement others impacting our business under its existing authority. CMS has also recently sought public comment on how best to leverage its authority provided under the Competitive Acquisition Program and introduce competition into Medicare Part B by allowing CMS to bring on vendors to negotiate payment amounts for Medicare Part B drugs. In addition, in August 2018, CMS issued new guidance that recognizes that Medicare Advantage (MA) plans may use step therapy (i.e., requiring the use of less costly medications before more costly medications are approved for coverage) for Part B drugs (such as EYLEA), beginning January 1, 2019, as part of a patient-centered care coordination program. CMS will also consider rulemaking related to step therapy that might be appropriate for 2020 and future years. On October 25, 2018, President Trump announced that CMS was evaluating a pilot program that proposes to set the Medicare payment amount for Part B single-source drugs and biologics to more closely align with international drug prices (also referred to as reference pricing) and pay physicians and hospitals participating in such program a set drug add-on payment for administered drugs. CMS also issued an advance notice of proposed rulemaking that requested public comment on the pilot program, which is proposed to initially cover fifty percent of Medicare Part B spending on separately payable Part B drugs (such as EYLEA). Congress and the U.S. administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are becoming increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures. In some cases, these measures are designed to encourage importation from other countries and bulk purchasing. A reduction in the availability or extent of reimbursement from U.S. government programs (including based on the proposals and initiatives described above) could have a material adverse effect on the sales of EYLEA or our other marketed products. Economic pressure on state budgets may also have a similar impact.

In addition, 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 our marketed products. If our marketed products are not included within an adequate number of formularies, adequate reimbursement levels are not provided, the eligible insured patient population for our products is limited, or a key payer refuses to provide reimbursement for our products in a particular jurisdiction altogether, this could have a material adverse effect on our and our collaborators' ability to

commercialize the applicable product.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our marketed 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 marketed products in foreign countries is limited or delayed.

Table of Contents

The commercial success of our products and product candidates is subject to strong competition.

Marketed Products

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. There is significant actual and potential future competition for each of our marketed products.

EYLEA. The market for eye disease products is very competitive. 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, and mCNV. In addition, we are aware of several companies developing biosimilar versions of EYLEA. For example, Momenta Pharmaceuticals (in partnership with Mylan) is developing M710 (currently in a pivotal trial in patients with DME). Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Formycon (in collaboration with Bioeq) is developing FYB201 (a Phase 3 trial in patients with wet AMD has been completed), Samsung Bioepis is developing SB11 (currently in a Phase 3 trial in patients with wet AMD), and Pfenex is developing PF582 (a Phase 1b/2a trial in patients with wet AMD has been completed).

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 Sciences' 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. Novartis is developing RTH258 (brolucizumab), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD and DME. Novartis announced in June 2017 that two Phase 3 studies of RTH258 met their primary endpoint of non-inferiority to EYLEA and has indicated that it is targeting approval by global regulatory authorities in 2019. Allergan is developing abicipar pegol for wet AMD and related conditions and announced in July 2018 that two Phase 3 studies of abicipar pegol met their primary endpoint of non-inferiority to Lucentis. Chengdu Kanghong Pharmaceutical Industry Group is conducting non-inferiority Phase 3 trials in the United States and Europe comparing conbercept, an anti-VEGF fusion protein, against EYLEA in wet AMD. Conbercept is approved in the wet AMD and myopic choroidal neovascularization indications in China. Genentech/Roche is developing a port delivery system implant for ranibizumab (currently in a Phase 3 study in patients with wet AMD). Kodiak Sciences is developing KSI-301, an anti-VEGF biologic therapy that is conjugated to a phosphorylcholine-based biopolymer to extend its half-life, for wet AMD, DME, and RVO. A Phase 1 study of KSI-301 in patients with DME met its primary safety and tolerability endpoint, and Kodiak has initiated a Phase 1b open label study in patients with wet AMD, DME, and RVO. In addition, 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, faricimab (RG7716), that targets both VEGF and Ang2 for wet AMD and DME (currently in Phase 3 non-inferiority studies comparing RG7716 against EYLEA in DME). Products that are being developed for use in combination with EYLEA and/or Lucentis may also pose a competitive threat. Opthea is developing OPT-302, a VEGFR-3 large molecule trap in combination with Lucentis in a Phase 2 trial for wet AMD. Santen (in partnership with TRACON) is developing DE-122, an anti-endoglin antibody in combination with Lucentis in a Phase 2 trial for wet AMD. Small-molecule tyrosine kinase inhibitors that have activity against VEGF may also compete against EYLEA, if approved for wet AMD and/or related conditions. Graybug is developing GB-102, an intravitreally administered depot formulation of the small molecule tyrosine kinase inhibitor, sunitinib, in a Phase 1/2 trial for wet AMD. PanOptica is developing PAN-90806, a topically administered tyrosine kinase inhibitor currently in a Phase 1/2 trial for wet AMD. Competitors are also developing other eye-drop formulations,

devices, oral therapies, and gene/cell therapies (such as REGENXBIO's RGX-314) 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 presents a significant competitive challenge for EYLEA in these indications. Avastin is also being evaluated in eye diseases in clinical trials in certain countries. Amgen (in collaboration with Allergan) has obtained regulatory approval of a biosimilar version of Avastin in the United States and the EU, and other competitors are also developing a biosimilar version of Avastin. Off-label use of any such biosimilar in one or more of the eye indications for which EYLEA is approved may put further pressure on the commercialization of EYLEA.

Table of Contents

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 diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye.

Dupixent. The market for Dupixent's current and potential future indications is competitive. In atopic dermatitis, Pfizer's Eucrisa, a topical ointment, competes with Dupixent and there are several other topical agents in development. In addition, a number of companies are developing antibodies against IL-13 for the treatment of atopic dermatitis, including LEO Pharma (in collaboration with AstraZeneca) with tralokinumab (currently in several Phase 3 trials) and Dermira (in collaboration with Genentech/Roche) with lebrikizumab (currently in a Phase 2b trial). Antibodies targeting OX40 are also in development for atopic dermatitis, with Glenmark Pharmaceuticals and Kyowa Hakko Kirin Co. conducting Phase 2 trials of their respective programs (GBR-830 and KHK4083). Galderma has completed a Phase 2b trial of nemolizumab, an antibody against IL-31R. XBiotech has completed a Phase 2 trial of bermekimab, an anti-IL-1alpha antibody. Novartis, in partnership with MorphoSys, has a Phase 2 trial in atopic dermatitis underway for MOR-106, an anti-IL-17C antibody. Kiniksa Pharmaceuticals has completed Phase 1 trials in atopic dermatitis for KPL-716, an antibody against the oncostatin M receptor beta. Orally administered small molecules are also being developed for atopic dermatitis, and, if approved, may compete with Dupixent in atopic dermatitis and other potential future indications. Several companies are studying JAK inhibitors for atopic dermatitis, including AbbVie's upadacitinib, Pfizer's abrocitinib (PF-04965842), Eli Lilly's baricitinib (recently reported to have met the primary endpoints of two atopic dermatitis Phase 3 studies), and Asana BioSciences' ASN002.

In asthma and potential future indications, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor such as GSK's Nucala, AstraZeneca's Fasenra, and Teva's Cinqair, all of which are approved for asthma in the United States and other jurisdictions. Novartis and Genentech/Roche's Xolair is also approved for asthma in multiple jurisdictions. Orally administered small molecule agents may also compete with Dupixent in asthma and potential future indications. For example, Novartis is developing fevipiprant, an oral prostaglandin D2 receptor 2 (CRTh2/DP2) antagonist, in multiple Phase 3 trials for asthma. Inhaled products may also compete with Dupixent in asthma and potential future indications, including Pieris Pharmaceuticals' PRS-060 (an anticalin being developed in partnership with AstraZeneca against IL-4R) and Novartis' CSJ117 (an antibody fragment against thymic stromal lymphopoietin).

There are several other potentially competitive products in development that may compete with Dupixent in both the atopic dermatitis and asthma indications, as well as potential future indications. For example, Amgen/AstraZeneca's tezepelumab, an antibody against thymic stromal lymphopoietin, or TSLP, is currently in Phase 3 development for asthma and Phase 2 trials in atopic dermatitis have been completed. Antibodies against the IL-33 ligand or the IL-33 receptor (ST2) may also be competitive with Dupixent across multiple indications. Phase 2 trials are ongoing in atopic dermatitis and asthma for etiokimab (ANB-020), an antibody against IL-33 developed by AnaptysBio. Genentech/Roche is developing RG6149, an anti-ST2 antibody, in Phase 2 trials for asthma and atopic dermatitis. GSK is developing GSK3772847, an anti-ST2 antibody, in a Phase 2 trial for asthma, and completed a Phase 1 trial that included atopic dermatitis patients.

Praluent. Amgen's Repatha has already received regulatory approvals in jurisdictions including the U.S., the EU, and Japan, and has captured a significant market share in certain jurisdictions. Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Repatha has also received regulatory approval for cardiovascular risk reduction. Other companies with development programs for injectables against PCSK9 include Alnylam Pharmaceuticals, Inc. (in collaboration with The Medicines Company), which has a clinical program underway with inclisiran, 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. These include bempedoic acid, which is being developed by Esperion Therapeutics, Inc. (currently in Phase 3 clinical development).

Kevzara. Genentech/Roche and Chugai are marketing an antibody against IL-6R (Actemra) for the treatment of rheumatoid arthritis that competes with Kevzara. In addition, several other companies, including R-Pharm JSC and BIOCAD, have antibodies against IL-6 or IL-6R in clinical development for rheumatoid arthritis. Biosimilar versions of Actemra may also compete with Kevzara, such as Mycenax's LuciNex (a Phase 1 trial has been completed). Further, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz, Eli Lilly's Olumiant, Gilead Sciences' filgotinib, Astellas Pharma's peficitinib, and AbbVie's upadacitinib may pose a competitive threat for Kevzara.

Libtayo. There are several competitors that are marketing or developing antibodies against PD-1 and/or PDL-1, including Bristol-Myers Squibb's Opdivo, Merck's Keytruda, Roche's Tecentriq, AstraZeneca's Imfinzi, Pfizer's Bavencio, Novartis' spartalizumab (PDR001), Celgene/BeiGene's tislelizumab (BGB-A317), GSK's dostarlimab (TSR-042), Agenus' AGEN2034, and Incyte's INCMGA0012.

See also Part I. Item 1. "Business - Competition" of this report.

Table of Contents

Product Candidates

Our other late-stage and earlier-stage clinical candidates in development are all fully human antibodies, which were generated using our VelocImmune technology. Our antibody generation technologies and other late-stage 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-based products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody-based product candidate against NGF. Competitors to evinacumab include Ionis Pharmaceuticals/Akcea Therapeutics' AKCEA-ANGPTL3-LRx, a ligand conjugated antisense drug against ANGPTL3, and Arrowhead Pharmaceuticals' ARO-ANG3, an RNAi therapeutic against ANGPTL3. We are also aware of several companies developing or marketing small molecules that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications.

See also Part I. Item 1. "Business - Competition" of this report.

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.

We rely on our collaborations with Bayer and Sanofi for commercializing EYLEA and Dupixent, Praluent, Kevzara, and Libtayo, respectively.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, 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, depending on the circumstances giving rise to termination), we rely on Bayer for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, while we have elected to co-promote Dupixent, Praluent, and Kevzara with Sanofi in the United States in accordance with the terms of our Antibody Collaboration, we continue to rely in part on Sanofi's sales and marketing organization in the United States for such products. Moreover, even though we lead commercialization efforts for Libtayo in the United States, Sanofi has exercised its option to co-promote Libtayo in the United States in accordance with the terms of our IO Collaboration. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of Dupixent, Praluent, Kevzara, or Libtayo (as applicable) may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent, Praluent, and Kevzara in the United States. For example, Sanofi records product sales for Dupixent, Praluent, and Kevzara in the United States, serves as the lead regulatory party for certain products and product candidates included in the Antibody Collaboration (e.g., is responsible for regulatory filings and negotiations relating to such products and product candidates) in the United States, and may lead negotiations with payors relating to such products and product candidates. We also rely on Sanofi for sales, marketing, and distribution of Dupixent, Praluent, Kevzara, and (in the future) Libtayo in countries outside the United States.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition 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, our Antibody Collaboration, or our IO Collaboration would create substantial new and

additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, 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 and "Risks Related to Our Reliance on Third Parties - If our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed" below.

Table of Contents

Sales of our marketed products recorded by us and our collaborators could be reduced by imports from countries where such products may be available at lower prices.

Our sales of products we commercialize in the United States and our collaborators' sales of products they commercialize under our collaboration agreements with them in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under the relevant collaboration agreements and, therefore, our results of operations) may be reduced if the applicable product 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 otherwise alter 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. Similarly, under our Antibody Collaboration and IO Collaboration with Sanofi, pricing and reimbursement for the products commercialized thereunder outside the United States are the responsibility of Sanofi. Prices for our marketed products in jurisdictions 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 our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United States. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced. 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 our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations.

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.

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 and Libtayo 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, 2018, product sales to two customers accounted on a combined basis for 92% 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 and Libtayo will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA and Libtayo 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.

Table of Contents

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.

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 (or are materially delayed in doing so), the value of our Company and our business, prospects, operating results, and financial condition will 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 for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

In certain instances (such as when we use a biomarker-based test to identify and enroll specific patients in a clinical trial), regulatory approval of a companion diagnostic to our therapeutic product candidate may be required as a condition to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays.

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.

Table of Contents

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 10-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 six 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 inspections 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 additional information, see "Risks Related to Manufacturing and Supply - Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring 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 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

Table of Contents

candidate (or prior or concurrent exposure to other products or product candidates), 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 the FDA's 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.

Furthermore, some of our products and product candidates (such as Libtayo and Dupixent) are studied in combination with agents and treatments developed by us or our collaborators. There may be additional risks and unforeseen safety issues resulting from such combined administration, any of which may materially adversely impact clinical development of these product candidates and our ability to obtain regulatory approval.

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 August 2017, we reported that the Phase 3 study evaluating suptavumab, an antibody to RSV, did not meet its primary endpoint of preventing medically-attended RSV infections in infants; as a result, we have discontinued further clinical development of this antibody. 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.

Many of our clinical trials are conducted under the oversight of independent Data Monitoring Committees (DMCs). 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 DMCs based on their review of such interim trial results. For example, in April 2018, the DMC monitoring the ongoing safety and efficacy of our Phase 3 clinical trials of fasinumab recommended that the higher dose-regimens be discontinued based on the risk-benefit assessment and that the program may continue with lower dose-regimens of fasinumab. As a result, the ongoing osteoarthritis trials have been modified accordingly and we discontinued dosing patients in the clinical study of fasinumab in chronic low back pain in patients with concomitant osteoarthritis of the knee and hip since this study was using only higher doses. The recommended termination or material modification of any of our ongoing late-stage clinical trials by a DMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our antibody-based product 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.

39

Table of Contents

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

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

With respect to EYLEA, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize EYLEA. 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 (IOI), sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), which can cause injury to the eye and other complications. The side effects previously reported for EYLEA include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. In addition, commercialization of EYLEA or our other products may be impacted by actions of third parties on which we rely, such as manufacturers of syringes or other devices used in the administration of our products. For example, in February 2018, we issued a letter to healthcare professionals providing updated guidance relating to reports of IOI following EYLEA injections. In this letter, we noted that while our review did not identify any association of IOI rates with the EYLEA drug itself, an association was seen with certain batches of the syringe that were included in specific lots of final packaged EYLEA kits. These and other complications or issues or side effects could harm further development and/or commercialization of EYLEA.

Dupixent is being studied in additional indications, including atopic dermatitis in pediatric patients, CRSwNP, and eosinophilic esophagitis. There is no guarantee that marketing approval of Dupixent in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include hypersensitivity reactions, conjunctivitis and keratitis, injection-site reactions, eye and eyelid inflammation, and cold sores. These and other complications or side effects could harm further development and/or commercialization of Dupixent.

Libtayo is also being studied in additional indications, as shown in the table under Part I, Item 1. "Business - Programs in Clinical Development." There is no guarantee that marketing approval of Libtayo in any of these indications will be successfully obtained. The side effects previously reported for Libtayo include certain immune-mediated adverse reactions, such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea.

There also are risks inherent in subcutaneous injections (which are used for administering our antibody-based products and product candidates, including Dupixent, Praluent, and Kevzara), 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 our antibody-based products and product candidates, including Dupixent, Praluent, or Kevzara.

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.

Table of Contents

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-based product 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.

Many of our products are intended to be used and, if approved, our product candidates may be used in combination with drug-delivery devices, which may result in additional regulatory and other risks.

Many of our products (including Dupixent, Praluent, and Kevzara) 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 and the additional risks resulting from a product candidate's designation as a combination product discussed below, our product candidates used with such drug-delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. The FDA review process and criteria for such applications is not a well-established area, which could also lead to delays in the approval process. 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.

In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic, or device. The determination whether a product is a combination product or two separately regulated products is made by the FDA on a case-by-case basis. Although a single marketing application is generally sufficient for the approval, clearance, or licensure of a combination product, the FDA may determine that separate marketing applications are necessary. In addition, submitting separate marketing applications may be necessary to receive some benefit that accrues only from approval under a particular type of application. This could significantly increase the resources and time required to bring a particular combination product to market.

Table of Contents

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property 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. 2,264,163 is the subject of opposition proceedings in the European Patent Office (EPO) (currently pending before its Boards of Appeal), as described in Note 17 to our Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (USPTO), the EPO, 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 review 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.

We also currently hold issued trademark registrations and have trademark applications pending in the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering, or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected.

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 (including those relating to trademarks, copyrights, and trade secrets). 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-based 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 and/or our collaborator Sanofi are currently party to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent and patent infringement proceedings relating to Dupixent, as described in Note 17 to our Consolidated Financial Statements. In addition, we are currently party to patent infringement proceedings initiated by us relating to our patents that concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Note 17 to our Consolidated Financial Statements.

We are aware of patents and pending patent applications owned by others that respectively claim antibodies to IL-4R and methods of treating conditions including atopic dermatitis and asthma with such antibodies; antibodies to IL-6R

and methods of treating conditions including rheumatoid arthritis with such antibodies; antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies; and antibodies to PD-1 and methods of treating cancer with such antibodies. In addition to Dupixent (dupilumab), Praluent (alirocumab), Kevzara (sarilumab), and Libtayo (cemiplimab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF, and evinacumab, an antibody to ANGPTL3.

Although we do not believe that any of our products or our late-stage antibody-based 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 products or our late-stage antibody-based product candidates, similar to the patent infringement proceedings 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 products or product candidates infringe such patents.

Table of Contents

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. For example, in August 2018, we and Sanofi entered into a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, and Ono Pharmaceutical to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo, as discussed further under Part I, Item 1. "Business - Marketed Products - Additional Information on 2018 Developments." If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business.

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

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

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property 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, biosimilar, and/or interchangeable 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 PPACA, 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 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 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 if, for example, the PPACA is amended.

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.

Table of Contents

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 Dupixent, Praluent, Kevzara, and Libtayo 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, Dupixent, Praluent, Kevzara, and Libtayo, and (b) our antibody-based product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody-based product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, 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.

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 own an approximately 445,000-square-foot facility in Limerick, Ireland, which we purchased and subsequently renovated to expand our manufacturing capacity and 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. 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 our marketed products, including EYLEA, Dupixent, Praluent, Kevzara, and Libtayo, 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 or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future, the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other 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 or our collaborators' manufacturing activities, or the activities of other 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

Table of Contents

apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of EYLEA, Dupixent, Praluent, Kevzara, or Libtayo 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 or our collaborators.

We have large-scale manufacturing operations in Rensselaer, New York and 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 or our collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results.

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

Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborator facilities. We and our collaborators would be unable to manufacture these materials if the relevant facility 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 or our collaborators 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 or our collaborators 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, contaminations, 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 or our collaborators' 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 or our collaborators are required to substitute for these sources to comply with European regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

Table of Contents

Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring 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 collaborators and other 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 facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. Our inability, or the inability of our collaborators and 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 Kevzara, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi fill-and-finish facility in Le Trait, France. While the BLA for Kevzara has since been approved by the FDA, this delayed the FDA approval of Kevzara. 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 our collaborators or other 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.

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.

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. Recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal anti-kickback statute.

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

Table of Contents

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.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that

all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Table of Contents

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

As a biopharmaceutical company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

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

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

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

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

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

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

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, government reimbursement changes and drug price control measures, and changes in the existing treaty and trade relationships with other countries), as evidenced by statements and actions of President Trump and certain members of Congress (including those discussed above under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - Sales of our marketed products 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"). 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. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could materially and adversely affect our business.

Table of Contents

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;
- 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, in a referendum held in the United Kingdom, voters have approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, the British government has been 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. We have large-scale manufacturing operations in Limerick, Ireland and have also established an office in the vicinity of London. 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, changes in tax laws and regulations, and tax effects of the accounting for stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control). 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.

On December 22, 2017, President Trump signed into law H.R.1., "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018" (also known as the "Tax Cuts and Jobs Act") (the Act). Most of the provisions of the Act went into effect on January 1, 2018. The Act includes a number of provisions that have impacted and are expected to continue to impact our operating results, cash flows, and financial condition, including reducing the U.S. federal corporate tax rate from 35% to 21%, changing the taxation of foreign earnings (including taxation of certain global intangible low-taxed income), allowing for a foreign-derived intangible income deduction and immediate expensing of qualified assets, repealing the deduction for domestic manufacturing, and imposing further limitations on the deductibility of executive compensation.

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

Table of Contents

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. (such as our consortium with a group of companies to fund the generation of genetic exome sequence data from the UK Biobank health resource) may implicate international data protection laws, including the General Data Protection Regulation (GDPR) that recently replaced the EU Data Protection Directive and is being enforced in the European Union. The GDPR has created a range of new compliance obligations, including increased transparency requirements and new data subject rights. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). In addition to the GDPR, certain EU Member States will be issuing their own implementation legislation. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving privacy and data protection laws. Complying with varying jurisdictional requirements could increase the costs and complexity of compliance, including the new risk of substantial financial penalties for data breach or improper processing of personal data under the GDPR. 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 and could create liability for us.

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 are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. 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, prevent, or substantially increase the cost of marketing and sales of any affected products that we are able to commercialize. 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 our Antibody Collaboration or our IO Collaboration with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.

We rely on funding and support from Sanofi to develop, manufacture, and commercialize certain of our products and product candidates. With respect to Dupixent, Praluent, Kevzara, and REGN3500, which we are co-developing with Sanofi under our Antibody Collaboration, Sanofi funds a significant portion of development expenses incurred in connection with the development of these products. In addition, we rely on Sanofi to lead much of the clinical development efforts, assist with or lead efforts to obtain and maintain regulatory approvals, and lead the commercialization efforts for these products and product candidates.

Table of Contents

As a result of the amendment and restatement of our IO Discovery and Development Agreement with Sanofi (which forms part of our IO Collaboration), we will fund and conduct on our own all research, development, manufacturing, and commercialization activities to support all of our immuno-oncology product candidates other than REGN4018 and REGN5458, unless we enter into arrangements with other parties. In addition, if Sanofi does not elect to co-develop REGN4018 or REGN5458 under our IO Collaboration, or opts out of their development under our IO Collaboration, we will be required to fund and conduct on our own all such efforts to support those product candidates, unless we enter into arrangements with other parties.

If Sanofi elects to co-develop REGN5458 and/or REGN4018 under our IO Collaboration, Sanofi will initially fund almost all of the development expenses incurred in connection with the development of REGN5458, for which Sanofi will be the principal controlling party, and half of the development expenses incurred in connection with the clinical development of REGN4018, for which we will be the principal controlling party. Under our IO Collaboration, Sanofi also funds half of the development expenses incurred in connection with the clinical development of Libtayo, subject to an agreed-upon development budget. In addition, for REGN5458, we will rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we will rely on Sanofi to lead (i) the commercialization efforts in the United States for REGN5458 and (ii) the commercialization efforts outside the United States to support Libtayo, REGN4018, and REGN5458.

If Sanofi terminates the Antibody Collaboration or the IO Collaboration or fails to comply with its payment obligations under any of our collaborations, 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 Dupixent, Praluent, and Kevzara, or our IO Collaboration, such as Libtayo (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 Antibody Collaboration or the IO Collaboration would create substantial new and additional risks to the successful development and commercialization of (i) Dupixent, Praluent, and Kevzara and (ii) Libtayo, respectively, 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 commercialize EYLEA outside the United States would be materially harmed.

We rely heavily on Bayer with respect to the commercialization of EYLEA outside the United States. Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing 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 pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to 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 may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the commercialization of EYLEA outside the United States and result in substantial additional costs and/or lower revenues 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 commercialization

of EYLEA outside the United States.

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

We depend upon third-party collaborators, including Sanofi, Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third-party manufacturers, fill/finish providers, 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 (including as a result of its inability to perform due to financial or other relevant constraints) or in

Table of Contents

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; and George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, 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 impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information 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. 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.

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.

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, our share of the profits from Bayer's sales of EYLEA outside the United States, funding we receive under our collaboration agreements, 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.

Table of Contents

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 our marketed products and the potential commercial launches of our product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody-based 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, in March 2017, we completed a $720.0 million lease financing for 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, which will become due and payable in full on the five-year anniversary of the closing date unless extended with the consent of all the participants and subject to certain other conditions. Our ability to refinance or 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 our marketed products, 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, 2018, we had $1,467.7 million in cash and cash equivalents and $3,097.2 million in marketable securities (including $88.0 million in equity securities). Our investments consist primarily of debt securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity

investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

Table of Contents

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:

- net product sales of our marketed products (as recorded by us or our collaborators), in particular EYLEA, Dupixent, and Libtayo, as well as our overall operating results;
- 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 the market share for, our marketed products, especially EYLEA, Dupixent, and Libtayo;
- whether our net product 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 EPO and in the USPTO;
- 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 (i.e., a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient);
- 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 (note, however, that we have agreed to grant a limited waiver of the requirement that Sanofi maintain the Highest Percentage Threshold (as defined below) as

a condition to its director designation right during the term of the letter agreement with Sanofi described below under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management"). As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of

Table of Contents

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, 2018, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 44.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2018. As of December 31, 2018, Sanofi beneficially owned 23,654,384 shares of our Common Stock, representing approximately 22.1% 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 are subject to a "lock-up" and may not be sold until December 20, 2020 (other than with respect to an aggregate of up to 1,173,847 shares, as to which we have agreed to waive the lock-up during the term of the letter agreement with Sanofi described below under "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management" and which currently remain available to be sold in accordance with the letter agreement). 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 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 (including, in the case of Sanofi, as a result of the lock-up waiver referred to above), 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, 2018, holders of Class A Stock held 15.1% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of December 31, 2018:

- our current executive officers and directors beneficially owned 9.7% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2018, and 20.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2018; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 44.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2018. In addition, these five shareholders plus our Chief Executive Officer held approximately

50.5% 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, 2018.

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.

Table of Contents

In addition, 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 (other than during the term of the letter agreement described below) 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) (which occurred in April 2014), and (ii) 25% of our outstanding shares of Class A Stock and Common Stock (taken together) (Highest Percentage Threshold). This designee is required to be "independent" of our Company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi. The current Sanofi designee, N. Anthony Coles, M.D., is a Class II director whose current term expires at the 2020 annual shareholder meeting.

Effective January 7, 2018, we and Sanofi and certain of Sanofi's direct and indirect subsidiaries entered into a letter agreement in connection with (a) the increase of the development budget amount for Libtayo set forth in the IO License and Collaboration Agreement and (b) the allocation of additional funds to certain proposed activities relating to the Dupilumab/REGN3500 Eligible Investments. Pursuant to the letter agreement, we have agreed, among other things, to grant a limited waiver of Sanofi's obligation to maintain the Highest Percentage Threshold during the term of the letter agreement in order to allow Sanofi to satisfy in whole or in part (a) its funding obligations with respect to the Libtayo development costs under the IO License and Collaboration Agreement for the quarterly periods commencing on October 1, 2017 and ending on September 30, 2020 by selling up to 800,000 shares of our Common Stock directly or indirectly owned by Sanofi (of which 584,613 currently remains available) and (b) its funding obligations with respect to the costs incurred by or on behalf of the parties to the Antibody License and Collaboration Agreement with respect to the Dupilumab/REGN3500 Eligible Investments for the quarterly periods commencing on January 1, 2018 and ending on September 30, 2020 by selling up to 600,000 shares of our Common Stock directly or indirectly owned by Sanofi (of which 589,234 currently remains available). If Sanofi desires to sell shares of our Common Stock during the term of the letter agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. In addition, we and Sanofi have agreed that, upon termination of the letter agreement, the amended and restated investor agreement will be amended to define "Highest Percentage Threshold" as the lower of (i) 25% of our outstanding shares of Class A Stock and Common Stock (taken together) and (ii) the higher of (a) Sanofi's percentage ownership of Class A Stock and Common Stock (taken together) on such termination date and (b) the highest percentage ownership of our outstanding shares of Class A Stock and Common Stock (taken together) Sanofi attains following such termination date.

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 of 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."

Table of Contents

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, pursuant to our 2016 ANG2 license and collaboration agreement with Bayer (which was terminated on November 1, 2018 by agreement of the parties but whose "standstill" provisions continue to be in effect as described below), 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). This prohibition will remain in place until the earliest of (i) November 1, 2023; (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 (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 option awards issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, our 2014 Long-Term Incentive Plan, and our Amended and Restated 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 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 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.

Table of Contents

Tarrytown, New York

At our Tarrytown, New York location, we lease approximately 1,467,000 square feet of laboratory and office space, of which approximately 1,180,000 square feet is occupied by Regeneron. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Tarrytown, New York Leases" for further details. We also own 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.

Sleepy Hollow, New York

We own an office building in Sleepy Hollow, New York, consisting of approximately 383,000 square feet. This facility is being used 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 565,000 square feet of research, manufacturing, office, and warehouse space. In 2018, we also purchased approximately 124,000 square feet of research and office space near our Rensselaer facility, a portion of which we had previously leased. We also own approximately 130 acres of land near our Rensselaer facility; we developed approximately 212,000 square feet on this property in connection with expanding our warehouse space, and we have plans to further develop this property in connection with expanding certain manufacturing activities.

Troy, New York

We own an office building in Troy, New York, consisting of approximately 217,000 square feet, which we are utilizing as additional office space to support the growth of our existing Rensselaer facilities.

Limerick, Ireland

We own a manufacturing facility in Limerick, Ireland, consisting of approximately 445,000 square feet, which was purchased and subsequently renovated to accommodate and support our growth and expand our manufacturing capacity. The facility has received certain manufacturing approvals by regulatory agencies, including the FDA.

ITEM 3. LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to the information set forth in Note 17 to our Consolidated Financial Statements included in this report.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

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.

As of January 31, 2019, there were 180 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.

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) the NASDAQ US Benchmark Pharmaceuticals Total Return Index (NQ US Pharma TR Index), and (ii) Standard & Poor's 500 Stock Index (S&P 500) for the period from December 31, 2013 through December 31, 2018. The comparison assumes that $100 was invested on December 31, 2013 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.

	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Regeneron	$ 100.00	$ 149.05	$ 197.24	$ 133.37	$ 136.59	$ 135.70
S&P 500	$ 100.00	$ 111.39	$ 110.58	$ 121.13	$ 144.65	$ 135.63
NQ US Pharma TR Index	$ 100.00	$ 121.82	$ 128.44	$ 127.04	$ 152.96	$ 163.37

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.

Table of Contents

Item 6. Selected Financial Data

The selected financial data set forth below for the years ended December 31, 2018, 2017, and 2016 and as of December 31, 2018 and 2017 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, 2015 and 2014 and as of December 31, 2016, 2015, and 2014 are derived from our audited financial statements not included in this report. Certain prior year amounts have been reclassified to conform to the current year's presentation.

	Year Ended December 31,				
(In millions, except per share data)	2018	2017	2016	2015	2014
Statement of Operations Data:					
Revenues:					
Net product sales	$4,106.2	$3,718.5	$3,338.4	$2,689.5	$1,750.8
Sanofi and Bayer collaboration revenue	2,187.8	1,815.3	1,403.0	1,339.4	1,036.9
Other revenue	416.8	338.4	119.0	74.8	31.9
	6,710.8	5,872.2	4,860.4	4,103.7	2,819.6
Expenses:					
Research and development	2,186.1	2,075.1	2,052.3	1,620.6	1,271.4
Selling, general, and administrative	1,556.2	1,320.4	1,177.7	838.5	519.3
Cost of goods sold	180.0	202.5	194.6	241.7	129.0
Cost of collaboration and contract manufacturing	254.1	194.6	105.1	151.0	76.0
	4,176.4	3,792.6	3,529.7	2,851.8	1,995.7
Income from operations	2,534.4	2,079.6	1,330.7	1,251.9	823.9
Other income (expense), net	19.1	(1.1)	(0.9)	(26.8)	(62.7)
Income before income taxes	2,553.5	2,078.5	1,329.8	1,225.1	761.2
Income tax expense [1]	(109.1)	(880.0)	(434.3)	(589.0)	(423.1)
Net income	$2,444.4	$1,198.5	$895.5	$636.1	$338.1
Net income per share - basic	$22.65	$11.27	$8.55	$6.17	$3.36
Net income per share - diluted	$21.29	$10.34	$7.70	$5.52	$2.98

	As of December 31,				
(In millions)	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash, cash equivalents, and marketable securities (current and non-current)	$4,564.9	$2,896.0	$1,902.9	$1,677.4	$1,360.6
Total assets	11,734.5	8,764.3	6,973.5	5,609.1	3,837.7
Convertible senior notes (current and non-current)	—	—	—	10.8	146.8
Capital and facility lease obligations (current and non-current)	708.5	703.5	481.1	364.7	312.3
Stockholders' equity	8,757.3	6,144.1	4,449.2	3,654.8	2,550.3

[1] Income taxes for the year ended December 31, 2018 includes the $162.1 million net impact of the Company's sale of non-inventory related assets between foreign subsidiaries. As a result of the Tax Cuts and Jobs Act being signed into law in December 2017, income taxes for the year ended December 31, 2017 included a charge of $326.2 million related to the re-measurement of our U.S. net deferred tax assets at the lower enacted corporate tax rate. See Note 16 to our Consolidated Financial Statements for further details.

60

Table of Contents

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

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

Overview

We are a fully integrated biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. Our commercialized medicines and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neuromuscular diseases, infectious diseases, and rare diseases.

As described in Part I, Item 1. "Business," we currently have seven products that have received marketing approval and 21 product candidates in clinical development, all of which were discovered in our research laboratories. Also refer to Part I, Item 1. "Business" for a summary of key events in 2018 and 2019 to date, and plans for the remainder of 2019, related to our clinical programs.

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 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 EYLEA, Dupixent, Praluent, Kevzara, and Libtayo. 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.

Table of Contents

Revenue Recognition

During the first quarter of 2018, we adopted Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers. Under the terms of the new standard, revenue is measured as the amount of consideration we expect to be entitled to in exchange for transferring promised goods or providing services to a customer, and is recognized when (or as) we satisfy performance obligations under the terms of a contract.

Product Revenue

Product sales consist of U.S. sales of EYLEA, Libtayo, and ARCALYST. We record revenue from product sales upon delivery to our distributors and specialty pharmacies (collectively, our customers). Revenue from product sales is recognized at a point in time when our customer is deemed to have obtained control of the product, which generally occurs upon receipt by our customers.

The amount of revenue we recognize from product sales varies due to rebates, chargebacks, and discounts provided under governmental and other programs, distribution-related fees, and other sales-related deductions. In order to determine the transaction price, we estimate, utilizing the expected value method, the amount of variable consideration that we will be entitled to. This estimate is based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, estimated payer mix, 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. Refer to the "Results of Operations - Revenues - Net Product Sales" section below for further details regarding our provisions, and credits/payments, for sales-related deductions.

Collaboration Revenue

We have entered into various agreements related to our activities to research, develop, manufacture, and commercialize product candidates and utilize our technology platforms. We earn collaboration revenue in connection with collaboration agreements to utilize our technology platforms and develop and/or commercialize product candidates. Depending on the terms of the arrangement, we may defer the recognition of all or a portion of the consideration received because the performance obligations are satisfied over time.

Our collaboration agreements may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In agreements involving multiple goods or services promised to be transferred to a customer, we must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation.

At the inception of the contract, the transaction price reflects the amount of consideration we expect to be entitled to in exchange for transferring promised goods or services to our customer. We review our estimate of the transaction price each period, and make revisions to such estimates as necessary. In arrangements where we satisfy performance obligation(s) during the development phase over time, we recognize collaboration revenue over time typically using an input method on the basis of our research and development costs incurred relative to the total expected cost which determines the extent of our progress toward completion. Due to the variability in the scope of activities and length of time necessary to develop a drug product, potential delays in development programs, changes to development plans and budgets as programs progress, including if we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to our estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future.

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 certain of our collaboration agreements, product sales and cost of sales may be recorded by our collaborators as they are deemed to be the principal in the transaction. We share in any profits or losses arising from the commercialization of such products, and record our share of the variable consideration, representing net product sales less cost of goods sold and shared commercialization and other expenses, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborator. 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

Table of Contents

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.

In arrangements where the collaborator records product sales, we may be obligated to use commercially reasonable efforts to supply commercial product to our collaborators, and may be reimbursed for our manufacturing costs as commercial product is shipped to our collaborators; however, recognition of such cost reimbursements as collaboration revenue is deferred until the product is sold by our collaborators to third-party customers.

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 noncancelable 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, restricted stock awards, and restricted stock units 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 stock 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 option awards granted and the amount of stock-based compensation recognized in future periods.

Table of Contents

Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns, including deferred tax assets and liabilities for expected amounts of global intangible low-taxed income (GILTI) inclusions. 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, 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. 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.

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.

Table of Contents

Results of Operations

Net Income

	Year Ended December 31,		
(In millions, except per share data)	2018	2017	2016
Revenues	$6,710.8	$5,872.2	$4,860.4
Operating expenses	(4,176.4)	(3,792.6)	(3,529.7)
Other income (expense), net	19.1	(1.1)	(0.9)
Income before income taxes	2,553.5	2,078.5	1,329.8
Income tax expense	(109.1)	(880.0)	(434.3)
Net income	$2,444.4	$1,198.5	$895.5
Net income per share - diluted	$21.29	$10.34	$7.70

Revenues

	Year Ended December 31,			Increase (Decrease)	
(In millions)	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Net product sales in the United States:					
EYLEA	$4,076.7	$3,701.9	$3,323.1	$374.8	$378.8
Libtayo	14.8	—	—	14.8	—
ARCALYST	14.7	16.6	15.3	(1.9)	1.3
Sanofi and Bayer collaboration revenue:					
Sanofi	1,111.1	877.2	658.7	233.9	218.5
Bayer	1,076.7	938.1	744.3	138.6	193.8
Other revenue	416.8	338.4	119.0	78.4	219.4
Total revenues	$6,710.8	$5,872.2	$4,860.4	$838.6	$1,011.8

Net Product Sales

Net product sales of EYLEA in the United States increased in 2018 compared to 2017 and 2016 due to higher sales volume, partly offset by an increase in sales-related deductions primarily due to payer sales mix and new rebate and discount programs. In addition, on September 28, 2018, the FDA approved Libtayo for the treatment of patients with metastatic or locally advanced CSCC. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2015	$ 6.4	$ 48.4	$ 0.5	$55.3
Provisions	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
Provisions	167.8	194.1	46.4	408.3
Credits/payments	(150.6)	(189.5)	(28.7)	(368.8)
Balance as of December 31, 2017	29.9	34.1	21.3	85.3
Provisions	223.4	211.0	44.5	478.9
Credits/payments	(212.2)	(203.1)	(57.5)	(472.8)
Balance as of December 31, 2018	$ 41.1	$ 42.0	$ 8.3	$91.4

Table of Contents

Sanofi Collaboration Revenue

	Year Ended December 31,		
(In millions)	2018	2017	2016
Antibody:			
Reimbursement of Regeneron research and development expenses - Discovery Agreement	—	$130.0	$130.0
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	$265.3	378.4	434.9
Reimbursement of Regeneron commercialization-related expenses	417.2	368.8	305.9
Regeneron's share of losses in connection with commercialization of antibodies	(227.0)	(442.6)	(459.0)
Other	103.5	119.1	28.4
Total Antibody	559.0	553.7	440.2
Immuno-oncology:			
Reimbursement of Regeneron research and development expenses - Discovery Agreement	154.4	138.8	86.5
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	157.4	101.2	52.0
Reimbursement of Regeneron commercialization-related expenses	8.9	7.0	—
Other	231.4	76.5	80.0
Total Immuno-oncology	552.1	323.5	218.5
Total Sanofi collaboration revenue	$1,111.1	$877.2	$658.7

Antibodies

The lower reimbursement of antibody research and development costs in 2018 compared to 2017 and 2016 was partly due to the Company's Discovery and Preclinical Development Agreement with Sanofi ending on December 31, 2017 without any extension and, therefore, no further funding from Sanofi under the Antibody Discovery Agreement after 2017. In addition, the lower reimbursement of antibody research and development costs during 2018 compared to 2017 was primarily related to the timing of recognition of revenue related to clinical manufacturing for Dupixent and a lower proportion of development reimbursements for Dupixent that Sanofi is required to fund under our License and Collaboration Agreement (for example, following receipt of positive Phase 3 results or U.S. regulatory approval). The lower reimbursement of antibody research and development costs under our License and Collaboration Agreement in 2017, compared to 2016, was also primarily due to a lower proportion of development reimbursements for Dupixent as described above.

In 2017, the FDA and the European Commission approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis. In October 2018, the FDA also approved Dupixent as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older. In 2017, the FDA and the European Commission approved Kevzara for the treatment of rheumatoid arthritis in adult patients.

Reimbursement of Regeneron antibody commercialization-related expenses represents reimbursement of internal and external costs incurred by Regeneron in connection with commercializing Praluent, Kevzara, and Dupixent.

Table of Contents

During 2018, 2017, and 2016, we and Sanofi shared commercial expenses related to Praluent, Kevzara, and Dupixent in accordance with the companies' License and Collaboration Agreement. As such, during the same periods in which we recorded reimbursements from Sanofi related to our commercialization expenses, we also recorded our share of combined losses in connection with the companies commercializing Praluent, Kevzara, and Dupixent within Sanofi collaboration revenue. During 2018, Sanofi collaboration revenues in connection with commercialization of antibodies were primarily impacted, compared to 2017, by our share of higher net sales of Dupixent (as the product was launched at the end of March 2017), and, to a lesser extent, Praluent and Kevzara. These increases in collaboration revenue were partly offset by an increase in the collaborations' Dupixent commercialization expenses for atopic dermatitis and the launch in asthma. In 2017, Sanofi collaboration revenues in connection with commercialization of antibodies were positively impacted, compared to 2016, by higher sales of collaboration antibody products, higher reimbursements of Dupixent commercialization-related expenses, and a decrease in the collaborations' Praluent commercialization expenses, which were partially offset by an increase in the collaborations' Kevzara commercialization expenses. See Part 1, Item 1. "Business - Marketed Products" for a summary of global net product sales recorded by Sanofi in connection with our Antibody License and Collaboration Agreement.

Other Sanofi antibody revenue in the table above primarily includes reimbursement of commercial supplies which were manufactured by the Company, and, in 2017, an acceleration of the recognition of deferred revenue from an $85.0 million up-front payment and other payments in connection with Sanofi's decision to end our Antibody Discovery Agreement.

Immuno-Oncology

Sanofi's reimbursement of immuno-oncology research and development costs under our IO License and Collaboration Agreement increased in 2018, compared to 2017 and 2016, due to an increase in clinical development activities for Libtayo. Reimbursement of Regeneron immuno-oncology commercialization-related expenses represents reimbursement of internal and external costs incurred by Regeneron in connection with commercializing Libtayo outside the United States.

Other Sanofi immuno-oncology revenue primarily includes recognition of a portion of the deferred revenue from $640.0 million of up-front payments received in 2015 in connection with the execution of the IO Collaboration agreements. This remaining portion of deferred revenue from the up-front payments is expected to be recognized as revenue over the remaining period the Company is obligated to satisfy its performance obligation in connection with performing development activities.

In 2018, we recorded cumulative catch-up adjustments to revenue of $135.0 million (included in other Sanofi immuno-oncology revenue in the table above) arising from changes in the estimate of the stage of completion of the collaborations' immuno-oncology programs, primarily in connection with the recent Amended IO Discovery Agreement (see Note 3 to our Consolidated Financial Statements).

Bayer Collaboration Revenue

	Year Ended December 31,		
(In millions)	2018	2017	2016
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$992.3	$802.3	$649.2
Reimbursement of Regeneron development expenses	10.8	31.1	27.3
Other	73.6	104.7	67.8
Total Bayer collaboration revenue	$1,076.7	$938.1	$744.3

Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below:

Table of Contents

	Year Ended December 31,		
(In millions)	2018	2017	2016
Net product sales outside the United States	$2,668.9	$2,226.9	$1,872.3
Regeneron's share of collaboration profit from sales outside the United States	$1,045.9	$856.1	$703.3
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(53.6)	(53.8)	(54.1)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$992.3	$802.3	$649.2

Bayer records revenue from sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profit, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter.

Other Bayer revenue in the table above primarily includes reimbursement of commercial supplies which were manufactured by the Company. In 2016, we 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), REGN910-3, for the treatment of ocular diseases or disorders. In 2017, we reported that results from two Phase 2 studies of REGN910-3 did not provide sufficient differentiation to warrant Phase 3 development; therefore, we recognized $37.4 million of revenue related to the acceleration of the recognition of the remaining amount of deferred revenue from the up-front payment received from Bayer.

Other Revenue

	Year Ended December 31,		
(In millions)	2018	2017	2016
Teva collaboration revenue:			
Reimbursement of Regeneron research and development expenses	$129.5	$115.1	$24.2
Other	115.1	106.4	13.7
Total Teva collaboration revenue	244.6	221.5	37.9
Other revenue	172.2	116.9	81.1
Total other revenue	$416.8	$338.4	$119.0

In 2016, we and Teva entered into a collaboration agreement to develop and commercialize fasinumab. In 2017, we recognized as revenue substantive development milestones of $25.0 million and $35.0 million from Teva, which are included in other Teva collaboration revenue in the table above.

In addition to Teva collaboration revenue, "Total other revenue" in the table above includes:

- Recognition of a portion of deferred revenue from up-front and other payments received from MTPC, including a portion related to the achievement of a $20.0 million development milestone in the third quarter of 2018, and, in 2017, recognition of a substantive development milestone of $30.0 million from MTPC, in connection with our fasinumab collaboration.
- Sanofi's reimbursement for manufacturing commercial supplies of ZALTRAP and a percentage of aggregate net sales of ZALTRAP under the terms of the Amended ZALTRAP Agreement.
- Recognition of revenue related to the $165.0 million up-front payment we received in August 2010, which was deferred upon receipt and was being recognized as revenue through mid-2018, in connection with the VelocImmune license agreement with Astellas. In accordance with the terms of the license agreement, Astellas terminated the agreement effective June 2018.
- Royalties in connection with a June 2009 agreement with Novartis, under which we receive royalties on worldwide sales of Novartis' Ilaris® (canakinumab). The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed $1.5 billion, and we are entitled to royalties until Novartis ceases sale of products subject to royalty.
- Recognition of revenue in connection with our agreement with BARDA to develop, test, and manufacture an antibody therapy (REGN3470-3471-3479) for the treatment of Ebola virus infection.
- Recognition of revenue in connection with sequencing of samples by the RGC for its customers.

The $416.8 million in total other revenue for 2018 also includes the impact of adopting ASC 606, Revenue from Contracts with Customers, in 2018 as the new standard has resulted in certain changes to the timing of revenue recognition related to our collaboration

Table of Contents

agreements. Prior period amounts have not been adjusted in connection with the adoption of this standard. See Note 1 to our Consolidated Financial Statements.

Expenses

	Year Ended December 31,			Increase (Decrease)	
(In millions, except headcount data)	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Research and development	$2,186.1	$2,075.1	$2,052.3	$111.0	$22.8
Selling, general, and administrative	1,556.2	1,320.4	1,177.7	235.8	142.7
Cost of goods sold	180.0	202.5	194.6	(22.5)	7.9
Cost of collaboration and contract manufacturing	254.1	194.6	105.1	59.5	89.5
Total operating expenses	$4,176.4	$3,792.6	$3,529.7	$383.8	$262.9
Average headcount	6,906	5,780	4,927	1,126	853

Our average headcount in 2018 increased compared to 2017 principally in connection with expanding our manufacturing activities and, to a lesser extent, increased research and development activities and the launches of Libtayo and Dupixent for asthma in the United States. Average headcount in 2017 increased compared to 2016 principally in connection with expanding our manufacturing activities.

Operating expenses in 2018, 2017, and 2016 included a total of $427.4 million, $507.3 million, and $559.9 million, respectively, of non-cash compensation expense related to employee stock options and restricted stock. The decrease in total non-cash compensation expense in 2018, compared to 2017, is largely attributable to a revision in our estimate of the number of stock options that are expected to be forfeited, partly offset by the immediate recognition of non-cash compensation expense in connection with annual employee grants made in December 2018 to certain retirement-eligible employees. As of December 31, 2018, unrecognized non-cash compensation expense related to outstanding stock options and unvested restricted stock was $702.6 million and $124.4 million, respectively. We expect to recognize this non-cash compensation expense related to stock options and restricted stock over weighted-average periods of 1.9 years and 4.6 years, respectively.

Research and Development Expenses

The following table summarizes our estimates of direct research and development expenses by clinical development program and other significant categories of research and development expenses. Direct research and development expenses are comprised primarily of costs paid to third parties for clinical and product development activities, including costs related to preclinical research activities, clinical trials, drug filling, packaging, and labeling, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse. Indirect research and development expenses have not been allocated directly to each program, and primarily consist of costs to compensate personnel, overhead and infrastructure costs to maintain our facilities, costs to manufacture bulk drug product (including pre-launch commercial supplies which were not capitalized as inventory) at our manufacturing facilities, and other costs related to activities that benefit multiple projects.

Table of Contents

(In millions)	Year Ended December 31, 2018	2017*	2016*	Increase (Decrease) 2018 vs. 2017	2017 vs. 2016
Direct research and development expenses:					
Dupixent (dupilumab)	$127.3	$199.9	$221.6	$(72.6)	$(21.7)
Libtayo (cemiplimab)	193.6	114.2	40.5	79.4	73.7
Fasinumab	199.9	153.8	110.4	46.1	43.4
Praluent (alirocumab)	64.7	84.9	85.6	(20.2)	(0.7)
Other product candidates in clinical development and other research programs	293.2	288.6	391.3	4.6	(102.7)
Total direct research and development expenses	878.7	841.4	849.4	37.3	(8.0)
Indirect research and development expenses:					
Payroll and benefits	606.7	578.5	556.1	28.2	22.4
Clinical manufacturing costs	358.6	388.2	404.9	(29.6)	(16.7)
Lab supplies, licensing, and other research and development costs	95.4	62.9	51.6	32.5	11.3
Occupancy and other operating costs	246.7	204.1	190.3	42.6	13.8
Total indirect research and development expenses	1,307.4	1,233.7	1,202.9	73.7	30.8
Total research and development expenses	$2,186.1	$2,075.1	$2,052.3	$111.0	$22.8

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

"Direct research and development expenses - Other product candidates in clinical development and other research programs" in 2016 included the $75.0 million up-front payment made in connection with the license and collaboration agreement with Intellia. Research and development expenses included non-cash compensation expense of $229.0 million, $271.9 million, and $313.0 million in 2018, 2017, and 2016, respectively.

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." There is also variability in the duration and costs necessary to develop a pharmaceutical product, potential opportunities and/or uncertainties related to future indications to be studied, and the estimated cost and scope of the projects. 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. 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 in 2018, compared to 2017, primarily due to higher headcount and headcount-related costs, higher contributions to independent not-for-profit patient assistance organizations, an increase in commercialization-related expenses for Dupixent, and, to a lesser extent, Libtayo, and an accrual for loss contingencies associated with ongoing litigation. Selling, general, and administrative expenses increased in 2017, compared to 2016, primarily due to (i) an increase in commercialization-related expenses associated with Dupixent and EYLEA, and, to a lesser extent, Kevzara and Libtayo, partly offset by lower commercialization-related expenses associated with Praluent, and (ii) higher headcount and headcount-related costs. Selling, general, and administrative expenses also included $169.2 million, $208.4 million, and $231.2 million of non-cash compensation expense in 2018, 2017, and 2016, respectively.

Table of Contents

Cost of Goods Sold

Cost of goods sold decreased slightly in 2018, compared to 2017, principally due to a decrease in period costs for our Limerick manufacturing facility as a result of higher commercial manufacturing activities. Cost of goods sold increased slightly in 2017, compared to 2016, principally due to an increase in start-up costs for our Limerick manufacturing facility, offset due to the fact that, effective May 2016, we were no longer obligated to pay royalties to Genentech based on U.S. sales of EYLEA.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing primarily includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer. The increase in cost of collaboration and contract manufacturing in 2018, compared to 2017, was impacted primarily due to the recognition of manufacturing costs associated with higher sales of Sanofi collaboration antibodies. These increases were partly offset by lower expenses recorded in connection with validating our Limerick manufacturing facility and lower inventory write-offs and reserves.

Cost of collaboration and contract manufacturing increased in 2017, compared to 2016, primarily due to costs we incurred in connection with validating our Limerick manufacturing facility related to products that are in collaboration with Sanofi, partly offset by the fact that 2016 included royalties payable to Genentech based on sales of EYLEA outside the United States (which ended in May 2016). Cost of collaboration and contract manufacturing was also adversely impacted by inventory write-offs and reserves totaling $57.2 million in 2017 primarily related to product that no longer met quality specifications, compared to $11.2 million in 2016.

Other Income (Expense)

Other income (expense), net, in 2018 increased compared to 2017 primarily due to increased interest income earned on available-for-sale debt securities due to higher average investment balances and rising interest rates. In addition, other expenses in 2017 included the recognition of a $30.1 million loss on debt extinguishment related to the 2017 Tarrytown lease transaction. See Note 12 to our Consolidated Financial Statements. The increase in other income in 2018 was partly offset by the recognition of unrealized losses on equity securities. In the first quarter of 2018, we adopted Accounting Standards Update (ASU) 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which requires us to measure equity investments at fair value with changes in fair value recognized in net income; previously, such changes in fair value were recognized in Other comprehensive income (loss).

Income Taxes

	Year Ended December 31,		
(In millions, except effective tax rate)	2018	2017	2016
Income tax expense	$(109.1)	$(880.0)	$(434.3)
Effective tax rate	4.3 %	42.3 %	32.7 %

On December 22, 2017, the bill known as the "Tax Cuts and Jobs Act" (the Act) was signed into law. The Act, which became effective with respect to most of its provisions as of January 1, 2018, includes a number of provisions that impact us, including reducing the U.S. federal corporate income tax rate from 35% to 21%, changing the taxation of foreign earnings (including taxation of certain global intangible low-taxed income (GILTI)), allowing for a foreign-derived intangible income deduction and immediate expensing of the cost for qualified assets, repealing the deduction for domestic manufacturing, and imposing further limitations on the deductibility of executive compensation. Changes in tax rates and tax laws are accounted for in the period of enactment. Therefore, as a result of the Act being signed into law, we recognized a provisional charge of $326.2 million in the fourth quarter of 2017 related to the re-measurement of our U.S. net deferred tax assets at the lower enacted corporate tax rate. The provisional charge recorded in the fourth quarter of 2017 was an estimate and was subject to further analysis, interpretation, and clarification of the Act. During 2018, we recorded an income tax benefit of $68.0 million as a final adjustment to the provisional amount recorded as of December 31, 2017.

Our effective tax rate for 2018 was positively impacted, compared to the U.S. federal statutory rate, primarily by the sale of non-inventory related assets between foreign subsidiaries (for which we recorded a $162.1 million net income tax benefit), and, to a lesser extent, the federal tax credit for research activities, stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and tax planning in connection

with the Act. The 2017 effective tax rate was negatively impacted by the provisional charge recorded as a result of the Act being signed into law (as described above), and was partly offset by the tax benefit associated with stock-based compensation. 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, partly offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate.

Table of Contents

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	As of December 31, 2018	2017	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	$1,467.7	$812.7	$655.0
Marketable securities - current	1,342.2	596.8	745.4
Marketable securities - noncurrent	1,755.0	1,486.5	268.5
	$4,564.9	$2,896.0	$1,668.9
Working capital:			
Current assets	$6,447.6	$4,335.0	$2,112.6
Current liabilities	1,442.8	1,135.5	307.3
	$5,004.8	$3,199.5	$1,805.3

As of December 31, 2018, we also had borrowing availability of $750.0 million under a revolving credit facility (see further description under "Credit Facility" below).

In addition, and as described in Part 1, Item 1. "Business - Collaborations - Collaborations with Sanofi," we and Sanofi recently entered into an Amended IO Discovery Agreement, pursuant to which Sanofi made a payment of $461.9 million to us in the first quarter of 2019.

Sources and Uses of Cash for the Years Ended December 31, 2018, 2017, and 2016

(In millions)	Year Ended December 31, 2018	2017	2016	Increase (Decrease) 2018 vs. 2017	2017 vs. 2016
Cash flows provided by operating activities	$2,195.1	$1,307.1	$1,485.9	$888.0	$(178.8)
Cash flows used in investing activities	$(1,463.0)	$(1,005.2)	$(1,046.8)	$(457.8)	$41.6
Cash flows used in financing activities	$(77.1)	$(24.4)	$(700.5)	$(52.7)	$676.1

Cash Flows from Operating Activities

2018. Our net income of $2,444.4 million in 2018 included (i) non-cash compensation expense of $427.4 million, (ii) the recognition of cumulative catch-up adjustments of $135.0 million within revenue primarily in connection with the Amended IO Discovery Agreement, and (iii) other non-cash items, including $75.8 million in connection with Sanofi satisfying its Libtayo development funding obligation in shares of Regeneron stock (see "Sanofi Funding of Certain Development Costs" below) and $41.9 million related to unrealized losses (net) on equity securities. Deferred tax assets as of December 31, 2018 increased by $140.0 million, compared to December 31, 2017, primarily due to the impact of the Company's sale of non-inventory related assets between foreign subsidiaries.

2017. Our net income of $1,198.5 million in 2017 included non-cash compensation expense of $507.3 million. Deferred tax assets as of December 31, 2017 decreased by $318.8 million, compared to December 31, 2016, primarily due to the re-measurement of our U.S. net deferred tax assets at the lower enacted corporate tax rates pursuant to the Act (as described in "Results of Operations - Income Taxes") and additional tax depreciation, partly offset by an increase in deferred tax assets related to stock-based compensation. Cash flows from operating activities for the year ended December 31, 2017 were negatively impacted by $926.5 million in connection with changes in other assets and liabilities. Included in such change was a decrease in deferred revenue by $113.1 million compared to December 31, 2016, partly due to the acceleration of the recognition of deferred revenue in connection with the Sanofi Antibody Discovery Agreement and the Bayer Ang2 agreement; see "Results of Operations - Revenues" section above for further details.

Table of Contents

2016. Our net income of $895.5 million 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 stock-based compensation, the tax basis of intangible assets, and deferred revenue. 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.

Cash Flows from Investing Activities

Capital expenditures were $383.1 million, $272.6 million, and $511.9 million in 2018, 2017, and 2016, respectively. Capital expenditures increased in 2018, compared to 2017, primarily due to higher capital expenditures in connection with renovations and additions at our Limerick, Ireland and Rensselaer, New York manufacturing facilities, and laboratory expansion and renovations at our Tarrytown, New York facilities.

We expect to incur capital expenditures of $410 million to $490 million in 2019 primarily in connection with expanding a portion of our manufacturing facilities at our Rensselaer, New York facility, continued renovations and expansion of our Limerick, Ireland facility, and laboratory expansion and renovations at our Tarrytown, New York facilities.

Cash Flows from Financing Activities

In 2017, proceeds in connection with capital and facility lease obligations relate to our receipt of $57.0 million in connection with the March 2017 lease transaction as described below under "Tarrytown, New York Leases". In 2016, we paid an aggregate amount of $643.4 million to warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants.

Credit Facility

In December 2018, 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), and contemporaneously terminated our then-existing credit agreement (the Prior Credit Agreement). The Credit Agreement was entered into on terms substantially similar to those of the Prior Credit Agreement. No borrowings were outstanding under the Prior Credit Agreement at the time of its termination.

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 $50.0 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 December 2023, 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, 2018.

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, 2018.

Sanofi Funding of Certain Development Costs

As described in Part 1, Item 1. "Business - Collaborations - Collaborations with Sanofi," effective January 7, 2018, we and Sanofi entered into a Letter Agreement in connection with, among other matters, increasing the development budget amount for Libtayo and allocating additional funds to certain proposed activities relating to dupilumab and REGN3500. Pursuant to the Letter Agreement, we have agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development and/or Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares (of which 1,173,847 shares remain available to be sold as of December 31, 2018) of our Common Stock directly or indirectly owned by Sanofi through September 30, 2020. If Sanofi desires

to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. During 2018, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 215,387 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently,

Table of Contents

we recorded $75.8 million related to the shares received as Treasury Stock during 2018. In addition, during 2018, Sanofi elected to sell, and we elected to purchase (in cash), 10,766 shares of the Company's Common Stock in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments. Consequently, we recorded the cost of the shares received, or $4.4 million, as Treasury Stock during 2018.

Tarrytown, New York Leases

We lease laboratory and office facilities in Tarrytown, New York (the Facility). In 2016, we entered into a Purchase Agreement with the then lessor, pursuant to which we agreed to purchase the Facility for a purchase price of $720.0 million. In March 2017, we entered into a Participation Agreement with Banc of America Leasing & Capital LLC (BAL), as lessor, and a syndicate of lenders (collectively, the Participants), which provided for lease financing in connection with the acquisition by BAL of the Facility and our lease of the Facility from BAL. In March 2017, we assigned our right to take title to the Facility under the Purchase Agreement to BAL, and the Participants advanced $720.0 million, which was used by BAL to finance the purchase price for the Facility.

Concurrent with entering into the Participation Agreement, we also entered into a lease agreement (the Lease) for the Facility with BAL for a five-year term. The Lease requires us to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month London Interbank Offered Rate (LIBOR), plus an applicable margin that varies with our debt rating and total leverage ratio.

The Participation Agreement and the Lease include an option for us to elect to extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. We also have the option prior to the end of the term of the Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Participation Agreement, all accrued and unpaid interest and yield thereon, and all other outstanding amounts under the Participation Agreement, the Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL. The advances under the Participation Agreement mature, and all amounts outstanding thereunder will become due and payable in full at the end of the term of the Lease.

The Participation Agreement and the Lease contain financial and operating covenants, which are substantially similar to the covenants set forth in our Credit Facility. We were in compliance with all covenants of the Participation Agreement and the Lease as of December 31, 2018.

Funding Requirements

The amount required 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 Part I, Item 1. "Business - Collaborations," 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.

Table of Contents

The following table summarizes our contractual obligations as of December 31, 2018.

		Payments Due by Period			
(In millions)	Total	Less than one year	1 to 3 years	3 to 5 years	Greater than 5 years
Purchase and other obligations [1]	$1,794.2	$936.9	$649.8	$180.1	$ 27.4
Capital and facility lease obligations [2]	89.7	26.4	56.3	7.0	—
Operating leases	25.4	10.4	7.2	3.7	4.1
Total contractual obligations	$1,909.3	$973.7	$713.3	$190.8	$ 31.5

[1] Purchase and other obligations primarily relate to research and development commitments, including those related to clinical trials, and capital expenditures. Our obligation to pay certain of these amounts may increase or be reduced based on relevant future events.

[2] 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 Consolidated Financial Statements. Amounts in the table above exclude the purchase price we would be obligated to pay if we were to exercise our option to purchase the Facility.

Liabilities for unrecognized tax benefits, totaling $189.5 million at December 31, 2018, 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. Under certain collaboration agreements, the amount of funding for reimbursement of research and development costs that we are entitled to receive is capped at a specified amount; therefore, we may elect to independently fund certain research and development costs in excess of such capped amounts.

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.

We anticipate continuing to incur substantial commercialization costs for EYLEA, Dupixent, Praluent, Kevzara, and Libtayo. Commercialization costs over the next few years will depend on, among other things, the market potential for product candidates, whether commercialization costs are shared with a collaborator, and regulatory approval of additional product candidates.

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

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, inclusive of our percentage on product sales in Japan) otherwise payable to us, unless, in the case of EYLEA, we elect to reimburse these expenses at a faster rate. As of December 31, 2018, our contingent reimbursement obligation to Bayer for EYLEA was approximately $265 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration and IO Collaboration was approximately $2.786 billion and $58 million, respectively. Therefore, we expect that, for

Table of Contents

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 Dupixent, Praluent, and Kevzara 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 related to our investments, and we do not currently use interest rate derivative instruments to manage exposure to interest rate changes of our investments. We estimate that a 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $27.7 million and $23.2 million decrease in the fair value of our investment portfolio as of December 31, 2018 and 2017, respectively.

We have exposure to market risk for changes in interest rates, including the interest rate risk relating to our March 2017 variable rate Tarrytown, New York lease (as described in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Tarrytown, New York Leases"). Our interest rate exposure is primarily offset by our investments in marketable securities. In addition, we further manage our interest rate exposure through the use of derivative instruments. All of our derivative instruments are utilized for risk management purposes and are not used for trading or speculative purposes. We continue to monitor our interest rate risk and may utilize additional derivative instruments and/or other strategies in the future to further mitigate our interest rate exposure.

We have hedged a portion of our floating interest rate exposure using interest rate swap and interest rate cap contracts (see Note 6 to our Consolidated Financial Statements). We estimate that a 100 basis point, or 1%, unfavorable change in interest rates would not have a material impact on the fair value of our interest rate swap or interest rate cap contracts. The following table summarizes the notional amounts of our outstanding interest rate swap and cap contracts as of December 31, 2018:

(In millions)	Notional Amount
Interest rate swap contracts	$ 75.0
Interest rate cap contracts	$ 75.0

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. In 2018, 2017, and 2016, we did not record any charges for other-than-temporary impairments of our available-for-sale debt securities.

We are subject to credit risk associated with the receivables due from our collaborators Bayer, Sanofi, and Teva. We are also subject to credit risk in connection with trade accounts receivable from our product sales. These trade accounts receivable are primarily 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. During 2018, 2017, and 2016, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. As of December 31, 2018 and 2017, three customers accounted on a combined basis for 99% of our net trade accounts receivables.

76

Table of Contents

Foreign Exchange Risk

As discussed further above, Bayer markets EYLEA outside the United States and Sanofi markets Dupixent, Praluent, and Kevzara 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, in addition to incurring expenses outside of the United States in connection with our international operations. Therefore, significant changes in foreign exchange rates of the countries outside the United States where our product is sold, where development expenses are incurred by us or our collaborators, or where we incur operating expenses 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.

Market Price Risk

We are exposed to price risk on equity securities included in our investment portfolio. Our marketable securities include equity investments in publicly traded stock of companies, including common stock of companies with which we have entered into collaboration arrangements. Changes in the fair value of our equity investments are included in Other income (expense), net on the Consolidated Statements of Income. For the year ended December 31, 2018, there were $41.9 million of net unrealized losses on equity securities recognized in Other income (expense), net.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this Item are included on pages F-1 through F-47 of this report. The supplementary financial information required by this Item is included at page F-47 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, as amended (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, 2018 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, 2018. The effectiveness of the Company's internal control over financial reporting as of December 31, 2018 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.

Table of Contents

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, 2018 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 2019 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 2019 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 2019 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 2019 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 2019 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.

Table of Contents

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.)
10.1 +	Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 13, 2011.)
10.1.1 +	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed December 16, 2005.)
10.1.2 +	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed December 16, 2005.)
10.1.3 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed December 13, 2004.)
10.1.5 +	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.)
10.1.6 +	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.)
10.1.7 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2010, filed February 17, 2011.)
10.1.8 +	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2010, filed February 17, 2011.)
10.1.9 +	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2011, filed February 21, 2012.)
10.1.10 +	Amendment No. 1 to the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended

	December 31, 2013, filed February 13, 2014.)
10.2 +	Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 12, 2017.)

Table of Contents

10.2.1	+	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.2	+	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.3	+	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.4	+	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.5	+	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2015, filed February 11, 2016.)
10.2.6	+	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2015, filed February 11, 2016.)
10.2.7	+	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.8	+	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.9	+	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.10	+	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2015, filed February 11, 2016.)
10.2.11	+	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Amended and Restated 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, 2017, filed February 8, 2018.)
10.2.12	+	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to the Registrant's executive officers under the Amended and Restated 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, 2017, filed February 8, 2018.)

10.2.13 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Amended and Restated 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, 2017, filed February 8, 2018.)
10.2.14 +	Form of stock option agreement and related notice of grant for use in connection with the grant of incentive stock options to P. Roy Vagelos, M.D. under the Amended and Restated 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, 2017, filed February 8, 2018.)

Table of Contents

10.2.15 +	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 Amended and Restated 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, 2017, filed February 8, 2018.)
10.2.16 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Amended and Restated 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, 2017, filed February 8, 2018.)
10.2.17 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised).
10.2.18 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised).
10.2.19 +	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 Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised).
10.2.20 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised).
10.2.21 +	Form of restricted stock unit award agreement and related notice of grant for use in connection with the grant of restricted stock units to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised).
10.3 +	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2008, filed February 26, 2009.)
10.4* +	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2004, filed March 11, 2005.)
10.5 +	Offer Letter for Robert E. Landry effective September 9, 2013. (Incorporated by reference from the Form 8-K for the Registrant, filed September 12, 2013.)
10.6 +	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2008, filed February 26, 2009.)
10.7 +	Regeneron Pharmaceuticals, Inc. Cash Incentive Bonus Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 17, 2015.)
10.8*	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2009, filed August 4, 2009.)
10.9*	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.)
10.10*	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.)
10.10.1*	Restated Amendment Agreement, dated December 30, 2014 and entered into effective as of May 7, 2012, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)
10.11	

	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.)
10.12*	Amended and Restated Discovery and Preclinical Development Agreement, dated as of November 10, 2009, by and between Aventis Pharmaceuticals Inc. and the Registrant. (Incorporated by reference from the Form 10-K/A for the Registrant, for the year ended December 31, 2009, filed June 2, 2010.)

Table of Contents

10.12.1*	Amendment No. 1 to Amended and Restated Discovery and Preclinical Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.13*	Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant. (Incorporated by reference from the Form 10-K/A for the Registrant, for the year ended December 31, 2009, filed June 2, 2010.)
10.13.1*	First Amendment to Amended and Restated License and Collaboration Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 1, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.13.2*	Amendment No. 2 to Amended and Restated License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.14	Amended and Restated Investor Agreement, dated as of January 11, 2014, by and among Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant. (Incorporated by reference from the Form 8-K for the Registrant, filed January 13, 2014.)
10.15*	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.)
10.16	Credit Agreement, dated as of December 14, 2018, by and among the Registrant, as a borrower and guarantor; certain direct 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., Fifth Third Bank, and MUFG Bank, Ltd., 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 December 17, 2018.)
10.17*	Amended and Restated Immuno-oncology Discovery and Development Agreement, executed on January 2, 2019 and effective as of December 31, 2018, by and between the Registrant and Sanofi Biotechnology SAS.
10.18*	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.)
10.19*	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.)
10.20*	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.)
10.21*	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.)
10.22*	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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2016, filed February 9, 2017.)

10.23	Participation Agreement, dated as of March 3, 2017, by and among Old Saw Mill Holdings LLC, as lessee; Bank of America, N.A., as administrative agent; BA Leasing BSC, LLC, as lessor; and the lenders party thereto from time to time. (Incorporated by reference from the Form 8-K for the Registrant, filed March 9, 2017.)
10.24	Lease and Remedies Agreement, dated as of March 3, 2017, between Old Saw Mill Holdings LLC, as lessee, and BA Leasing BSC, LLC, as lessor. (Incorporated by reference from the Form 8-K for the Registrant, filed March 9, 2017.)

Table of Contents

10.25	Guaranty, dated as of March 3, 2017, made by the Registrant, Regeneron Healthcare Solutions, Inc. and Regeneron Genetics Center LLC, as the initial guarantors. (Incorporated by reference from the Form 8-K for the Registrant, filed March 9, 2017.)
10.26 +	Retirement Agreement, effective as of January 5, 2018, by and between Regeneron Pharmaceuticals, Inc. and Robert J. Terifay. (Incorporated by reference from the Form 10-Q for the Registrant, filed May 3, 2018.)
10.27	Letter Agreement, dated as of January 7, 2018, by and among the Registrant, Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amérique du Nord, and Sanofi Biotechnology SAS. (Incorporated by reference from the Form 10-Q for the Registrant, filed May 3, 2018.)
21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page of this Annual Report on Form 10-K).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

+ Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

Table of Contents

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 7, 2019 By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Table of Contents

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, Executive 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 7, 2019
/s/ ROBERT E. LANDRY Robert E. Landry	Executive Vice President, Finance and Chief Financial Officer (Principal Financial Officer)	February 7, 2019
/s/ CHRISTOPHER R. FENIMORE Christopher R. Fenimore	Vice President, Controller (Principal Accounting Officer)	February 7, 2019
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	President, Chief Scientific Officer, and Director	February 7, 2019
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	Chairman of the Board	February 7, 2019
/s/ BONNIE L. BASSLER Bonnie L. Bassler, Ph.D.	Director	February 7, 2019
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	Director	February 7, 2019
/s/ N. ANTHONY COLES N. Anthony Coles, M.D.	Director	February 7, 2019
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	Director	February 7, 2019
/s/ CHRISTINE A. POON Christine A. Poon	Director	February 7, 2019
/s/ ARTHUR F. RYAN Arthur F. Ryan	Director	February 7, 2019

/s/ GEORGE L. SING George L. Sing	Director	February 7, 2019
/s/ MARC TESSIER-LAVIGNE Marc Tessier-Lavigne, Ph.D.	Director	February 7, 2019
/s/ HUDA Y. ZOGHBI Huda Y. Zoghbi, M.D.	Director	February 7, 2019

Table of Contents

REGENERON PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

	Page Numbers
Report of Independent Registered Public Accounting Firm	F- 2
Consolidated Balance Sheets at December 31, 2018 and 2017	F- 4
Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2018, 2017, and 2016	F- 5
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2018, 2017, and 2016	F- 6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2018, 2017, and 2016	F- 8
Notes to Consolidated Financial Statements	F- 9 to F- 47

Table of Contents

Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Regeneron Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive income; stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for revenues from contracts with customers in 2018.

Basis for Opinions

The Company's management is responsible for these consolidated 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 the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. 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.

Definition and Limitations of Internal Control over Financial Reporting

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

Table of Contents

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 7, 2019

We have served as the Company’s auditor since 1989.

Table of Contents

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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$1,467.7	$812.7
Marketable securities	1,342.2	596.8
Accounts receivable - trade, net	1,723.7	1,538.6
Accounts receivable from Sanofi	226.4	193.7
Accounts receivable from Bayer	293.1	242.0
Inventories	1,151.2	726.1
Prepaid expenses and other current assets	243.3	225.1
Total current assets	6,447.6	4,335.0
Marketable securities	1,755.0	1,486.5
Property, plant, and equipment, net	2,575.8	2,358.6
Deferred tax assets	828.7	506.3
Other noncurrent assets	127.4	77.9
Total assets	$11,734.5	$8,764.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$218.2	$178.2
Accrued expenses and other current liabilities	772.1	637.2
Deferred revenue from Sanofi	246.7	177.7
Deferred revenue - other	205.8	142.4
Total current liabilities	1,442.8	1,135.5
Capital and facility lease obligations	708.5	703.5
Deferred revenue from Sanofi	279.3	379.9
Deferred revenue - other	184.9	249.3
Other noncurrent liabilities	361.7	152.0
Total liabilities	2,977.2	2,620.2
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred Stock, $.01 par value; 30,0000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,911,354 in 2018 and 2017	—	—
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 111,084,951 in 2018 and 109,477,222 in 2017	0.1	0.1
Additional paid-in capital	3,911.6	3,512.9
Retained earnings	5,254.3	2,946.7
Accumulated other comprehensive (loss) income	(12.3)	0.6
Treasury Stock, at cost; 3,990,021 shares in 2018 and 3,763,868 shares in 2017	(396.4)	(316.2)
Total stockholders' equity	8,757.3	6,144.1

Total liabilities and stockholders' equity	$11,734.5	$8,764.3

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

Table of Contents

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

	Year Ended December 31,		
	2018	2017	2016
Statements of Operations			
Revenues:			
Net product sales	$4,106.2	$3,718.5	$3,338.4
Sanofi collaboration revenue	1,111.1	877.2	658.7
Bayer collaboration revenue	1,076.7	938.1	744.3
Other revenue	416.8	338.4	119.0
	6,710.8	5,872.2	4,860.4
Expenses:			
Research and development	2,186.1	2,075.1	2,052.3
Selling, general, and administrative	1,556.2	1,320.4	1,177.7
Cost of goods sold	180.0	202.5	194.6
Cost of collaboration and contract manufacturing	254.1	194.6	105.1
	4,176.4	3,792.6	3,529.7
Income from operations	2,534.4	2,079.6	1,330.7
Other income (expense):			
Other income (expense), net	47.3	24.0	6.3
Interest expense	(28.2)	(25.1)	(7.2)
	19.1	(1.1)	(0.9)
Income before income taxes	2,553.5	2,078.5	1,329.8
Income tax expense	(109.1)	(880.0)	(434.3)
Net income	$2,444.4	$1,198.5	$895.5
Net income per share - basic	$22.65	$11.27	$8.55
Net income per share - diluted	$21.29	$10.34	$7.70
Weighted average shares outstanding - basic	107.9	106.3	104.7
Weighted average shares outstanding - diluted	114.8	115.9	116.3
Statements of Comprehensive Income			
Net income	$2,444.4	$1,198.5	$895.5
Other comprehensive income (loss), net of tax:			
Unrealized (loss) gain on marketable securities	(7.0)	12.7	(21.4)
Unrealized gain on cash flow hedges	0.7	0.8	—
Comprehensive income	$2,438.1	$1,212.0	$874.1

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

Table of Contents

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2018, 2017, and 2016
(In millions)

	Class A Common Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2015	1.9	—	106.4	$ 0.1	$ 3,099.5	$ 852.7	$ 8.6	(3.6)	$ (306.1)	$ 3,654.8
Issuance of Common Stock in connection with exercise of stock options	—	—	1.7	—	115.2	—	—	—	—	115.2
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(0.3)	—	(143.2)	—	—	—	—	(143.2)
Issuance of Common Stock in connection with conversion of convertible notes	—	—	0.1	—	48.0	—	—	—	—	48.0
Issuance of Common Stock in connection with Company 401(k) Savings Plan	—	—	—	—	16.6	—	—	—	—	16.6
Stock-based compensation charges	—	—	—	—	574.9	—	—	—	—	574.9
Acquisition of Common Stock in connection with exercise of convertible note hedges	—	—	—	—	10.1	—	—	(0.2)	(10.1)	—
Reduction of warrants	—	—	—	—	(643.3)	—	—	—	—	(643.3)
Reduction of equity component of convertible notes	—	—	—	—	(47.8)	—	—	—	—	(47.8)
Net income	—	—	—	—	—	895.5	—	—	—	895.5
Other comprehensive loss, net of tax	—	—	—	—	—	—	(21.4)	—	—	(21.4)
Balance, December 31, 2016	1.9	—	107.9	0.1	3,030.0	1,748.2	(12.8)	(3.8)	(316.2)	4,449.3
Issuance of Common Stock in connection with exercise of stock options	—	—	2.3	—	240.6	—	—	—	—	240.6
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(0.8)	—	(301.7)	—	—	—	—	(301.7)
Issuance of restricted stock under Long-Term Incentive Plan	—	—	0.1	—	—	—	—	—	—	—
	—	—	—	—	19.4	—	—	—	—	19.4

Issuance of Common Stock in connection with Company 401(k) Savings Plan										
Stock-based compensation charges	—	—	—	—	524.6	—	—	—	—	524.6

Table of Contents

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Class A Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Net income	—	—	—	1,198.5	—	—	—	1,198.5
Other comprehensive income, net of tax	—	—	—	—	13.4	—	—	13.4
Balance, December 31, 2017	1.9	—	3,512.9	2,946.7	0.6	(3.8)	(316.2)	6,144.1
Issuance of Common Stock in connection with exercise of stock options	—	—	114.2	—	—	—	—	114.2
Common Stock tendered upon exercise of stock options and vesting of restricted stock in connection with employee tax obligations	—	—	(187.2)	—	—	—	—	(187.2)
Issuance of restricted stock under Long-Term Incentive Plan	—	—	—	—	—	—	—	—
Issuance of Common Stock in connection with Company 401(k) Savings Plan	—	—	26.9	—	—	—	—	26.9
Repurchases of Common Stock from Sanofi	—	—	—	—	—	(0.2)	(80.2)	(80.2)
Stock-based compensation charges	—	—	444.8	—	—	—	—	444.8
Cumulative-effect adjustment upon adoption of new accounting standards	—	—	—	(136.8)	(6.6)	—	—	(143.4)
Net income	—	—	—	2,444.4	—	—	—	2,444.4
Other comprehensive loss, net of tax	—	—	—	—	(6.3)	—	—	(6.3)
Balance, December 31, 2018	1.9	—	$3,911.6	$5,254.3	$ (12.3)	(4.0)	$(396.4)	$ 8,757.3

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

Table of Contents

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

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net income	$2,444.4	$1,198.5	$895.5
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	148.2	145.5	104.7
Non-cash compensation expense	427.4	507.3	559.9
Other non-cash items, net	12.1	63.5	45.1
Deferred taxes	(140.0)	318.8	(360.1)
Changes in assets and liabilities:			
Increase in Sanofi, Bayer, and trade accounts receivable	(268.9)	(362.7)	(143.8)
Increase in inventories	(387.9)	(314.2)	(149.8)
(Increase) decrease in prepaid expenses and other assets	(55.7)	(113.3)	36.1
(Decrease) increase in deferred revenue	(194.5)	(113.1)	244.3
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	210.0	(23.2)	254.0
Total adjustments	(249.3)	108.6	590.4
Net cash provided by operating activities	2,195.1	1,307.1	1,485.9
Cash flows from investing activities:			
Purchases of marketable and other securities	(1,845.5)	(1,277.2)	(809.4)
Sales or maturities of marketable securities	775.6	544.6	274.5
Capital expenditures	(383.1)	(272.6)	(511.9)
Other	(10.0)	—	—
Net cash used in investing activities	(1,463.0)	(1,005.2)	(1,046.8)
Cash flows from financing activities:			
Proceeds in connection with capital and facility lease obligations	—	57.0	5.1
Payments in connection with capital and facility lease obligations	—	(19.9)	(32.8)
Repayments of convertible senior notes	—	—	(12.9)
Payments in connection with reduction of outstanding warrants	—	—	(643.4)
Proceeds from issuance of Common Stock	114.5	240.2	126.7
Payments in connection with Common Stock tendered for employee tax obligations	(187.2)	(301.7)	(143.2)
Repurchases of Common Stock	(4.4)	—	—
Net cash used in financing activities	(77.1)	(24.4)	(700.5)
Net increase (decrease) in cash, cash equivalents, and restricted cash	655.0	277.5	(261.4)
Cash, cash equivalents, and restricted cash at beginning of period	825.2	547.7	809.1
Cash, cash equivalents, and restricted cash at end of period	$1,480.2	$825.2	$547.7
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	$22.3	$18.7	$5.5
Cash paid for income taxes	$205.6	$754.8	$481.4

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

Table of Contents

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

1. Business Overview and Summary of Significant Accounting Policies

Organization and Business

Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron," "Company," "we," "us," and "our") is a fully integrated biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. Our commercialized medicines and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neuromuscular diseases, infectious diseases, and rare diseases. The Company's products that have received marketing approval consist of EYLEA® (aflibercept), Dupixent® (dupilumab), Praluent® (alirocumab), Kevzara® (sarilumab), Libtayo® (cemiplimab), ARCALYST® (rilonacept), and ZALTRAP® (ziv-aflibercept). The Company is a party to collaboration agreements to develop and commercialize, as applicable, certain products and product candidates (see Note 3).

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

Basis of Presentation

The consolidated financial statements include the accounts of Regeneron and its wholly-owned subsidiaries. Intercompany balances and transactions are eliminated in consolidation. Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

We adopted Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, as of January 1, 2018. The Company adopted the standard using the modified retrospective method, and thus recognized a cumulative-effect adjustment to reduce Retained earnings and increase Deferred revenue on January 1, 2018 by $143.4 million, net of tax. Prior period amounts have not been adjusted in connection with the adoption of this standard.

The new standard did not have an impact on the recognition of revenue from product sales (see Note 2). However, the new standard has resulted in certain changes to the timing of revenue recognition related to our collaboration agreements (see Note 3). As a result of adopting ASC 606, non-refundable upfront payments, which were previously recognized ratably over the performance period, and substantive development milestones, which were previously recognized in the period when the milestone was achieved, will be recognized over the remaining performance period based on the Company's progress towards satisfying its identified performance obligation.

Table of Contents

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

The following tables summarize the impacts of adopting ASC 606 on the Company's consolidated financial statements as of and for the year ended December 31, 2018 compared with the guidance that was in effect before the change.

	December 31, 2018		
Balance Sheet Data	As Reported	Adjustments	Balance Without Adoption of ASC 606
Inventories	$1,151.2	$ 17.5	$1,168.7
Deferred tax assets	$828.7	$ 17.5	$846.2
Total assets	$11,734.5	$ 35.0	$11,769.5
Accrued expenses and other current liabilities	$772.1	$ (1.3)	$770.8
Deferred revenue from Sanofi (current)	$246.7	$ (93.0)	$153.7
Deferred revenue - other (current)	$205.8	$ (58.3)	$147.5
Total current liabilities	$1,442.8	$ (152.6)	$1,290.2
Deferred revenue from Sanofi (noncurrent)	$279.3	$ 163.2	$442.5
Deferred revenue - other (noncurrent)	$184.9	$ 21.8	$206.7
Total liabilities	$2,977.2	$ 32.4	$3,009.6
Retained earnings	$5,254.3	$ 2.6	$5,256.9
Total stockholders' equity	$8,757.3	$ 2.6	$8,759.9
Total liabilities and stockholders' equity	$11,734.5	$ 35.0	$11,769.5

	Year Ended December 31, 2018		
Consolidated Statement of Operations Data	As Reported	Adjustments	Balance Without Adoption of ASC 606
Sanofi collaboration revenue	$1,111.1	$ (163.8)	$947.3
Other revenue	$416.8	$ (31.7)	$385.1
Total revenues	$6,710.8	$ (195.5)	$6,515.3
Cost of collaboration and contract manufacturing	$254.1	$ (17.5)	$236.6
Income from operations	$2,534.4	$ (178.0)	$2,356.4
Income before income taxes	$2,553.5	$ (178.0)	$2,375.5
Income tax expense	$(109.1)	$ 37.2	$(71.9)
Net income	$2,444.4	$ (140.8)	$2,303.6

The Company also adopted Accounting Standards Update ("ASU") 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, as of January 1, 2018. The amendments require companies to measure equity investments at fair value with changes in fair value recognized in net income. Upon adoption, the Company recognized a cumulative-effect adjustment, related to unrealized gains on equity securities, to reduce Accumulated other comprehensive income and increase Retained earnings on January 1, 2018 by $6.6 million. See Note 4 and Note 5.

Table of Contents

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

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.

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. We invest our cash primarily in debt securities of investment grade institutions. We consider our investments in debt 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 available-sale-sale debt securities are included in Other income (expense), net. We also have investments in equity securities that are carried at fair value with changes in fair value recognized within Other income (expense), net. We have elected to measure certain equity investments we hold that do not have readily determinable fair values at cost less impairment, if any, and adjust for observable price changes in orderly transactions for identical or similar investments of the same issuer.

The Company reviews its portfolio of available-for-sale debt 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 an available-for-sale debt 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 trade "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.

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. 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 write down such unmarketable inventory to its estimated realizable value.

Table of Contents

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

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	10–50 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, Libtayo, and ARCALYST. Revenue from product sales is recognized at a point in time when our customer is deemed to have obtained control of the product, which generally occurs upon receipt by our distributors and specialty pharmacies. The Company's written contracts with its customers stipulate product is shipped freight on board destination (FOB destination).

The Company sells its marketed products in the United States to several distributors and specialty pharmacies. Under these distribution models, the distributors and specialty pharmacies generally take physical delivery of product. For EYLEA and Libatyo, the distributors and specialty pharmacies generally sell the product directly to healthcare providers.

The amount of revenue we recognize from product sales varies due to rebates, chargebacks, and discounts provided under governmental and other programs, distribution-related fees, and other sales-related deductions. In order to determine the transaction price, we estimate, utilizing the expected value method, the amount of variable consideration that we will be entitled to. This estimate is based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, estimated payer mix, and other relevant factors. The Company reviews its estimates of rebates, chargebacks, and other applicable provisions each period and records any necessary adjustments in the current period's net product sales.

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

providers and the chargebacks that customers have already claimed.

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

Table of Contents

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

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, 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 and Libtayo 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.

Other Sales-Related Deductions: The Company estimates discounts and other sales-related deductions offered to customers, group purchasing organizations, and end-user customers, based on written contracts. The Company estimates and records other sales-related deductions generally based on gross sales.

b. Collaboration Revenue

We have entered into various agreements related to our activities to research, develop, manufacture, and commercialize product candidates and utilize our technology platforms. The Company earns collaboration revenue in connection with collaboration agreements to utilize our technology platforms and develop and/or commercialize product candidates where we deem the collaborator to be our customer. As described above, during the first quarter of 2018, we adopted ASC 606. Under the terms of the new standard, revenue is measured as the amount of consideration we expect to be entitled to in exchange for transferring promised goods or providing services to a customer, and is recognized when (or as) we satisfy performance obligations under the terms of a contract. Depending on the terms of the arrangement, we may defer the recognition of all or a portion of the consideration received because the performance obligations are satisfied over time.

Our collaboration agreements may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In agreements involving multiple goods or services promised to be transferred to a customer, we must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation.

The terms of these agreements typically include consideration to be provided to the Company in the form of non-refundable up-front payments, development milestones, payments for development activities, as well as payments for commercialization activities, sales milestones, and sharing of profits or losses arising from the commercialization of products.

At the inception of the contract, the transaction price reflects the amount of consideration we expect to be entitled to in exchange for transferring promised goods or services to our customer. In arrangements where we satisfy performance obligation(s) during the development phase over time, we recognize collaboration revenue over time typically using an input method on the basis of our research and development costs incurred relative to the total expected cost which determines the extent of our progress toward completion. We review our estimate of the transaction price and the total expected cost each period, and make revisions to such estimates as necessary.

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.

Under certain of the Company's collaboration agreements, product sales and cost of sales may be recorded by the Company's collaborators as they are deemed to be the principal in the transaction. The Company shares in any profits or losses arising from the commercialization of such products, and records its share of the variable consideration, representing net product sales less cost of goods sold and shared commercialization and other expenses, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborator. Our collaborators provide us with estimates of our share of the profits or losses for such quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our share of the profit or loss is adjusted accordingly, as necessary

In arrangements where the collaborator records product sales, the Company may be obligated to use commercially reasonable efforts to supply commercial product to its collaborators, and may be 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

Table of Contents

product is sold by the Company's collaborators to third-party customers. In addition, we may also be reimbursed for a portion of costs incurred for other commercial-related activities, which are recorded as collaboration revenue in the period in which such costs are incurred.

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. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations ("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. 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 noncancelable 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

The Company recognizes stock-based compensation expense for grants of stock option, restricted stock awards, and restricted stock units under the Company's Long-Term Incentive Plans to employees and non-employee members of the Company's board of directors (as applicable) 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.

Table of Contents

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

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, including deferred tax assets and liabilities for expected amounts of global intangible low-taxed income ("GILTI") inclusions. 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 considers 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 under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, (ii) if applicable, 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) if applicable, Common Stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive.

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. 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. The Company has a concentration of credit risk associated with the receivables due from its collaborators Bayer, Sanofi, and Teva. The Company is also subject to credit risk with accounts receivable from its product sales, which are due from several distributors and specialty pharmacies (the Company's customers). As of December 31, 2018 and 2017, three individual customers accounted for 99% 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. As of December 31, 2018 and 2017, there were no reserves against trade accounts receivable. In addition, during the years ended December 31, 2018, 2017, and 2016, the Company did not recognize any charges for write-offs of trade accounts receivable.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02, Leases. The new standard requires a lessee to recognize on 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. We will adopt this new standard on January 1, 2019 (the "effective date") and use the effective date as our date of initial application. As such, we will not

adjust prior period amounts. Furthermore, we expect to elect the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under the new standard for leases that commenced prior to the effective date. We have substantially completed the process of analyzing and extracting relevant data from the Company's lease contracts. We are finalizing our evaluation of the impact that this guidance will have on our financial statements, including related disclosures, and expect to recognize additional right-of-use assets and corresponding lease liabilities related to operating leases of approximately $30 million as of January 1, 2019. We have also evaluated our facilities for which the Company has historically applied build-to-suit accounting, and do not expect a material impact on our

Table of Contents

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

financial statements upon adoption of the new standard. The ultimate impact that the new standard will have will depend on the total amount of the Company's lease commitments as of our first reporting period subsequent to the adoption date. We are also finalizing our implementation of a new lease accounting software system and updating our internal controls and processes.

2. Product Sales

Net product sales consist of the following:

	Year Ended December 31,		
Net Product Sales in the United States	2018	2017	2016
EYLEA	$4,076.7	$3,701.9	$3,323.1
Libtayo	14.8	—	—
ARCALYST	14.7	16.6	15.3
	$4,106.2	$3,718.5	$3,338.4

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the years ended December 31, 2018, 2017, and 2016. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Year Ended December 31,		
	2018	2017	2016
Besse Medical, a subsidiary of AmerisourceBergen Corporation	56%	51%	55%
McKesson Corporation	36%	29%	28%
Curascript SD Specialty Distribution, a subsidiary of Express Scripts	**	19%	16%

** Sales to Curascript SD Specialty Distribution represented less than 10% of total gross product revenue during the period.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts, distribution-related fees, and other sales-related deductions. Accruals for chargebacks and discounts are recorded as a direct reduction to accounts receivable. Accruals for rebates, distribution-related fees, and other sales-related deductions are recorded within accrued liabilities.

The following table summarizes the provisions, and credits/payments, for these sales-related deductions for the years ended December 31, 2018, 2017, and 2016.

	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2015	$ 6.4	$ 48.4	$ 0.5	$55.3
Provisions	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
Provisions	167.8	194.1	46.4	408.3
Credits/payments	(150.6)	(189.5)	(28.7)	(368.8)
Balance as of December 31, 2017	29.9	34.1	21.3	85.3
Provisions	223.4	211.0	44.5	478.9
Credits/payments	(212.2)	(203.1)	(57.5)	(472.8)
Balance as of December 31, 2018	$ 41.1	$ 42.0	$ 8.3	$91.4

Table of Contents

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

3. Collaboration and License Agreements

We have entered into various agreements related to our activities to research, develop, manufacture, and commercialize product candidates and utilize our technology platforms. Significant agreements of this kind are described below.

a. Sanofi

Sanofi owned a total of 23,654,384 shares of our Common Stock as of December 31, 2018, a portion of which was purchased in connection with the companies' antibody collaboration described below. See Note 13 for a description of the investor agreement between us and Sanofi.

The collaboration revenue we earned from Sanofi is detailed below:

	Year Ended December 31,		
Sanofi Collaboration Revenue	2018	2017	2016
Antibody:			
Reimbursement of Regeneron research and development expenses	$265.3	$508.4	$564.9
Reimbursement of Regeneron commercialization-related expenses	417.2	368.8	305.9
Regeneron's share of losses in connection with commercialization of antibodies	(227.0)	(442.6)	(459.0)
Other	103.5	119.1	28.4
Total Antibody	559.0	553.7	440.2
Immuno-oncology:			
Reimbursement of Regeneron research and development expenses	311.8	240.0	138.5
Reimbursement of Regeneron commercialization-related expenses	8.9	7.0	—
Other	231.4	76.5	80.0
Total Immuno-oncology	552.1	323.5	218.5
	$1,111.1	$877.2	$658.7

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 was 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 funded the Company's research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi agreed to fund the Company's research activities up to $130.0 million in both 2016 and 2017. The Company's Antibody Discovery Agreement with Sanofi ended on December 31, 2017 without any extension and, therefore, funding from Sanofi under the Antibody Discovery Agreement ceased after 2017. The Company accelerated the recognition of deferred revenue from the $85.0 million up-front payment and other payments in connection with Sanofi's decision to end the Antibody Discovery Agreement between the Company and Sanofi on December 31, 2017. The Company has the right to develop or continue to develop product candidates discovered under the Antibody Discovery Agreement, with the exception of those that are being developed (and commercialized, as applicable) under the Antibody License and Collaboration Agreement (Dupixent, Praluent, Kevzara, and REGN3500), independently, or with other collaborators.

Under the License and Collaboration Agreement, 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. The Company recognized as research and development expense $47.7 million, $91.8 million, and

F- 17

Table of Contents

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

$108.6 million in 2018, 2017, and 2016, respectively, its share of antibody development expenses that Sanofi incurred related to Praluent, Kevzara, and Dupixent. All other agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi. If the Antibody Collaboration becomes profitable, we will be obligated to reimburse Sanofi for 50% of worldwide development expenses that were fully funded by Sanofi and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products. However, the Company is only required to apply 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 $2.786 billion as of December 31, 2018.

Effective January 7, 2018, the Company and Sanofi entered into a letter agreement (the "Letter Agreement") in connection with, among other matters, the allocation of additional funds to certain activities relating to dupilumab and REGN3500 (collectively, the "Dupilumab/REGN3500 Eligible Investments"). Refer to the "Immuno-Oncology" section below for further details regarding the Letter Agreement. During 2018, Sanofi elected to sell, and we elected to purchase (in cash), 10,766 shares of the Company's Common Stock in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments. Consequently, we recorded the cost of the shares received, or $4.4 million, as Treasury Stock during 2018.

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. Sanofi leads commercialization activities for products developed under the License and Collaboration Agreement, subject to the Company's right to co-promote such products. The Company has exercised its option to co-promote Praluent, Kevzara, and Dupixent in the United States and thus far has not exercised any of its options to co-promote Praluent, Kevzara, and Dupixent outside the United States. 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 and loss sharing, the Company is entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales of antibodies (subject to this agreement) outside the United States exceed $1.0 billion on a rolling twelve-month basis.

"Reimbursement of Regeneron commercialization-related expenses" in the table above represents reimbursement of internal and external costs in connection with commercializing Praluent, Kevzara, and Dupixent. 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 commercializing Praluent, Kevzara, and Dupixent within Sanofi collaboration revenue. In March and September 2017, the U.S. Food and Drug Administration ("FDA") and the European Commission, respectively, approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis. In October 2018, the FDA also approved Dupixent as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. In May and June 2017, the FDA and the European Commission, respectively, approved Kevzara for the treatment of adult patients with rheumatoid arthritis.

With respect to each antibody product in 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 License and Collaboration Agreement contains other termination provisions, including for material breach by the other party. 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.

The Company's significant promised goods and services consist of providing research and development services, including the manufacturing of clinical supplies, and providing commercial-related services, including the

manufacturing of commercial supplies. As we recognize Sanofi antibody collaboration revenue in an amount equal to the amount we have the right to invoice and such amount corresponds directly with the value to Sanofi of our performance to date, we do not disclose the value of the transaction price allocated to our remaining unsatisfied performance obligations. The amount of variable consideration related to our share of profits and losses, as well as sales milestones, is deemed to be constrained as of December 31, 2018, and therefore has not been included in the transaction price.

Table of Contents

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

The following table summarizes accounts receivable and deferred revenue information in connection with the Company's Antibody Collaboration with Sanofi:

	As of December 31, 2018	2017
Accounts receivable	$138.2	$121.0
Deferred revenue	$236.1	$117.7

Significant changes in deferred revenue balances are as follows:

	Year Ended December 31, 2018
Increase due to shipments of commercial supplies to Sanofi	$ 251.6
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (133.2)

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 Amended and Restated Immuno-oncology Discovery and Development Agreement ("Amended IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). In connection with the execution of the original Immuno-oncology Discovery and Development Agreement in 2015 ("2015 IO Discovery Agreement"), which has been replaced by the Amended IO Discovery Agreement (as discussed below), Sanofi made a $265.0 million non-refundable up-front payment to the Company. Pursuant to the 2015 IO Discovery Agreement, the Company was to 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, and Sanofi was to reimburse the Company for up to $825.0 million ("IO Discovery Funding") of these costs, subject to certain annual limits. The original term of the 2015 IO Discovery Agreement was to continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget was 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.

Effective December 31, 2018, the Company and Sanofi entered into the Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company ("IO Development Activities") under the 2015 IO Discovery Agreement to developing therapeutic bi-specific antibodies targeting (i) BCMA and CD3 (the "BCMAxCD3 Program") and (ii) MUC16 and CD3 (the "MUC16xCD3 Program") through clinical proof of concept. The Amended IO Discovery Agreement provided for Sanofi’s payment of $461.9 million to the Company as consideration for (x) the termination of the 2015 IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the 2015 IO Discovery Agreement during the fourth quarter of 2018.

Under the terms of the Amended IO Discovery Agreement, the Company is required to conduct development activities with respect to (i) the BCMAxCD3 Program through the earlier of clinical proof-of-concept or the expenditure of $70.0 million (the "BCMAxCD3 Program Costs Cap") and (ii) the MUC16xCD3 Program through the earlier of clinical proof of concept or the expenditure of $50.0 million (the "MUC16xCD3 Program Costs Cap");

provided that under certain circumstances, Sanofi will have the option to increase the MUC16xCD3 Program Costs Cap to $70.0 million by making a payment to the Company in the amount of $20.0 million.

Pursuant to the Amended IO Discovery Agreement, we are primarily responsible for antibody development, preclinical activities, toxicology studies, manufacture of clinical supplies, filing of Investigational New Drug Applications ("INDs"), and clinical development through proof-of-concept. We are obligated to 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. However, the Company is only required to apply 10% of its share of the profits from IO Collaboration products in any calendar quarter towards

Table of Contents

reimbursing Sanofi for these development costs. The Company's contingent reimbursement obligation to Sanofi under the IO Collaboration was approximately $58 million as of December 31, 2018.

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when clinical proof-of-concept is established, the applicable Program Costs Cap is reached, or in certain other limited circumstances, Sanofi will have the option to license rights to the product candidate and other antibodies targeting the same targets for, with regard to BCMAxCD3, immuno-oncology indications, and with regard to MUC16xCD3, all indications, pursuant to the IO License and Collaboration Agreement, as amended. 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 receive a royalty on sales. Pursuant to the Amended IO Discovery Agreement, the parties agreed that (i) if Sanofi exercises its option with respect to a BCMAxCD3 Program antibody, Sanofi will lead the development and commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) the Company will lead the development of such MUC16xCD3 Program antibody and commercialization of such MUC16xCD3 Program antibody within the United States and (y) Sanofi will lead the commercialization of such MUC16xCD3 Program antibody outside of the United States.

The Amended IO Discovery Agreement provides that Regeneron retains exclusive rights to all other immuno-oncology programs that were part of the 2015 IO Discovery Agreement, provided that Sanofi will receive a royalty on global sales of two product candidates currently in clinical development, REGN3767 and REGN4659. The Amended IO Discovery Agreement will terminate as of the earlier of (a) Sanofi having elected to exercise or not exercise its options with respect to the BCMAxCD3 Program and the MUC16xCD3 Program in accordance with the terms of the Amended IO Discovery Agreement and (b) December 31, 2022.

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 BCMAxCD3 Program antibody or MUC16xCD3 Program antibody thereunder, it will co-develop these drug candidates with the Company through product approval. Sanofi will fund development costs up front for a BCMAxCD3 Program antibody and we will reimburse half of the total development costs for such antibody from our share of future IO Collaboration profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement provision described above. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for a MUC16xCD3 Program antibody.

Under the terms of the IO License and Collaboration Agreement, the parties are co-developing Libtayo (cemiplimab), an antibody targeting the receptor known as programmed cell death protein 1 (PD-1). The parties share equally, on an ongoing basis, agreed-upon development expenses for Libtayo. Pursuant to the Letter Agreement, the Libtayo development budget was increased and the Company has agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development and Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares of our Common Stock directly or indirectly owned by Sanofi through September 30, 2020. If Sanofi desires to sell shares of our Common Stock during the term of the Letter Agreement to satisfy a portion or all of its funding obligations for the Libtayo development and/or Dupilumab/REGN3500 Eligible Investments, we may elect to purchase, in whole or in part, such shares from Sanofi. If we do not elect to purchase such shares, Sanofi may sell the applicable number of shares (subject to certain daily and quarterly limits) in one or more open-market transactions. During 2018, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 215,387 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded the cost of the shares received, or $75.8 million, as Treasury Stock during 2018.

The Company has principal control over the development of Libtayo and leads 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. On September 28, 2018, the FDA approved Libtayo for the treatment of

patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC), and Sanofi has exercised its option to co-promote Libtayo in the United States. The Company will be entitled to a milestone payment of $375.0 million in the event that global sales of certain licensed products targeting PD-1 (including Libtayo), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with any of such licensed products targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period. The amount of variable consideration related to such milestone is deemed to be constrained as of December 31, 2018, and therefore has not been included in the transaction price.

In August 2018, we and Sanofi entered into a license agreement with Bristol-Myers Squibb Company, E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. to obtain a license under certain patents owned and/or exclusively licensed by one or more of those parties that includes the right to develop and sell Libtayo. Under the agreement, we and Sanofi made an up-front payment of $20.0 million and are obligated to pay royalties of 8.0% on worldwide sales of Libtayo through December 31, 2023,

Table of Contents

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

and royalties of 2.5% from January 1, 2024 through December 31, 2026. The up-front payment was shared, and the royalties are shared, equally by us and Sanofi.

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. 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 promised goods and services consisted of a license to certain rights and intellectual property and providing research and development services, including the manufacturing of clinical supplies. The Company concluded that the license was not distinct, primarily as a result of (i) Sanofi being unable to benefit on its own or together with other resources that are readily available as the license provides access to Regeneron's complex and specialized know-how and (ii) the research and development services, including manufacturing in support of such services, were expected to significantly modify the initial license. Therefore, the promised goods and services were considered a single performance obligation. Consequently, the $640.0 million in aggregate up-front payments made by Sanofi during 2015 in connection with the execution of the IO Collaboration has been recorded as deferred revenue and has been included in the transaction price at the inception of the contract. "Other" Sanofi immuno-oncology revenue in the Sanofi Collaboration Revenue table above primarily includes recognition of deferred revenue from the $640.0 million of up-front payments.

As it relates to the IO Collaboration, "Reimbursement of Regeneron commercialization-related expenses" in the table above represents reimbursement of costs by Sanofi in connection with the commercialization of Libtayo outside of the United States.

The following table summarizes accounts receivable and deferred revenue information in connection with the Company's IO Collaboration with Sanofi:

	As of December 31,	
	2018	2017
Accounts receivable	$77.9	$59.3
Deferred revenue	$289.9	$440.0

Significant changes in deferred revenue balances are as follows:

	Year Ended December 31, 2018
Increase as a result of cumulative-effect adjustment arising from the adoption of ASC 606	$93.6
Net decrease as a result of cumulative catch-up adjustments arising from changes in the estimate of the stage of completion	$(135.0)
Revenue recognized that was included in deferred revenue at the beginning of the period	$(108.7)

During 2018, we reduced our estimate of the total research and development costs expected to complete the contract, including in connection with entering into the Amended IO Discovery Agreement (as described above). The $135.0 million cumulative catch-up adjustments in the table above includes a $192.7 million adjustment related to the modification of the IO Discovery Agreement.

The aggregate amount of the transaction price under the IO Collaboration allocated to the Company's performance obligation that was unsatisfied (or partially unsatisfied) as of December 31, 2018 was $1,398.4 million. This amount is expected to be recognized as revenue over the remaining period the Company is obligated to satisfy its performance obligation in connection with performing development activities.

Table of Contents

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

b. Bayer

EYLEA outside the United States

Revenue earned in connection with our Bayer EYLEA collaboration is as follows (note that the table excludes amounts in connection with our Bayer Ang2 antibody and PDGFR-beta antibody collaboration agreements, which are described below):

	Year Ended December 31,		
Bayer EYLEA Collaboration Revenue	2018	2017	2016
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$992.3	$802.3	$649.2
Reimbursement of Regeneron EYLEA development expenses	11.2	13.3	9.0
Other	73.6	58.7	52.6
	$1,077.1	$874.3	$710.8

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. All agreed-upon EYLEA development expenses incurred by the Company and Bayer, under a global development plan, are 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 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 $265 million as of December 31, 2018.

Ang2 antibody and PDGFR-beta antibody outside the United States

In 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), REGN910-3, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment and paid a portion of our global development costs and development costs exclusively for the territory outside the United States. In the fourth quarter of 2017, the Company reported that results from two Phase 2 studies of REGN910-3 did not provide sufficient differentiation to warrant Phase 3 development. Therefore, during the fourth quarter of 2017, the Company recognized $37.4 million of revenue related to the acceleration of the recognition of the remaining amount of deferred revenue from the up-front payment (which was initially recorded as deferred revenue) received from Bayer as the Company deemed its performance obligation to be satisfied. On November 1, 2018, the Company and Bayer agreed to terminate this collaboration agreement.

In 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), REGN2176-3. Effective in the first quarter of 2017, the Company discontinued clinical development of REGN2176-3, and on July 31, 2017, the Company and Bayer agreed to terminate this collaboration agreement.

In 2017 and 2016, the Company recognized a total of $63.8 million and $33.5 million, respectively, of revenue in connection with its Ang2 and PDGFR-beta collaboration agreements with Bayer. Revenue recognized thereunder was not material in 2018.

Table of Contents

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

c. 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 our collaboration agreement with Mitsubishi Tanabe Pharma Corporation. In connection with the execution of the Teva Collaboration Agreement, Teva made a $250.0 million non-refundable up-front payment. The Company leads global development activities, and the parties share development costs equally, on an ongoing basis, under a global development plan.

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.

In 2017, the Company earned, and recognized as substantive milestones, development milestones of $25.0 million and $35.0 million, respectively, from Teva upon initiation of two Phase 3 trials. During 2018, the Company achieved a development milestone of $60.0 million. The Company is entitled to receive up to an aggregate of $340.0 million in additional development milestones and up to an aggregate of $1,890.0 million in contingent payments upon achievement of specified annual net sales amounts; the amount of variable consideration related to such milestones is deemed to be constrained as of December 31, 2018, and therefore has not been included in the transaction price.

At the inception of the Teva Collaboration Agreement, the Company's significant promised goods and services consisted of a license to certain rights and intellectual property and providing research and development services, including the manufacturing of clinical supplies. The Company concluded that the license was not distinct, primarily as a result of (i) Teva being unable to benefit from the license on its own or together with other resources that are readily available as the license providing access to Regeneron's complex and specialized know-how and (ii) the research and development services, including manufacturing in support of such services, were expected to significantly modify the initial license. Therefore, the promised goods and services were considered a single performance obligation. Consequently, the $250.0 million up-front payment and development milestones received or receivable from Teva, as described above, have been recorded as deferred revenue and have been included in the transaction price.

The Company recognized $244.6 million, $221.5 million, and $37.9 million of revenue in 2018, 2017, and 2016, respectively, in connection with the Teva Collaboration Agreement.

The following tables summarize accounts receivable and deferred revenue information in connection with the Teva Collaboration Agreement:

	As of December 31,	
	2018	2017
Accounts receivable (recorded within Prepaid expenses and other current assets)	$28.8	$71.3
Deferred revenue	$194.5	$197.4

Table of Contents

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

Significant changes in deferred revenue balances are as follows:

	Year Ended December 31, 2018
Increase as a result of cumulative-effect adjustment arising from the adoption of ASC 606	$ 48.2
Increase due to amounts invoiced, excluding amounts recognized as revenue during the period	$ 30.7
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (83.8)

The aggregate amount of the transaction price under the Teva Collaboration Agreement allocated to the Company's performance obligation that was unsatisfied (or partially unsatisfied) as of December 31, 2018 was $472.2 million. This amount is expected to be recognized as revenue over the remaining period the Company is obligated to satisfy its performance obligation in connection with performing development activities.

d. Other

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

Table of Contents

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

4. Marketable Securities

Marketable securities as of December 31, 2018 and 2017 consist of both available-for-sale debt securities of investment grade issuers (see below and Note 5) as well as equity securities of publicly traded companies (see Note 5).

The following tables summarize the Company's investments in available-for-sale debt securities:

As of December 31, 2018	Amortized Cost Basis	Unrealized Gains	Losses	Fair Value
Available-for-sale debt securities:				
Corporate bonds	$2,734.8	$1.0	$(17.4)	$2,718.4
U.S. government and government agency obligations	110.4	—	(1.0)	109.4
Sovereign bonds	7.6	—	—	7.6
Commercial paper	113.8	—	—	113.8
Certificates of deposit	60.0	—	—	60.0
	$3,026.6	$1.0	$(18.4)	$3,009.2
As of December 31, 2017				
Available-for-sale debt securities:				
Corporate bonds	$1,718.0	$2.2	$(7.7)	$1,712.5
U.S. government and government agency obligations	186.7	—	(1.2)	185.5
Municipal and sovereign bonds	4.6	—	—	4.6
Commercial paper	107.0	—	—	107.0
Certificates of deposit	11.0	—	—	11.0
	$2,027.3	$2.2	$(8.9)	$2,020.6

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of December 31, 2018 mature at various dates through November 2023. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	As of December 31,	
	2018	2017
Maturities within one year	$1,342.2	$593.8
Maturities after one year through five years	1,667.0	1,426.8
	$3,009.2	$2,020.6

Table of Contents

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

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

	Less than 12 Months		12 Months or Greater		Total	
As of December 31, 2018	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$1,482.6	$ (6.1)	$801.6	$ (11.3)	$2,284.2	$ (17.4)
U.S. government and government agency obligations	—	—	99.1	(1.0)	99.1	(1.0)
	$1,482.6	$ (6.1)	$900.7	$ (12.3)	$2,383.3	$ (18.4)
As of December 31, 2017						
Corporate bonds	$931.0	$ (4.9)	$256.8	$ (2.8)	$1,187.8	$ (7.7)
U.S. government and government agency obligations	110.5	(0.4)	67.9	(0.8)	178.4	(1.2)
	$1,041.5	$ (5.3)	$324.7	$ (3.6)	$1,366.2	$ (8.9)

There were no other-than-temporary impairment charges recorded with respect to the Company's investments during 2018 and 2017. 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.

Realized gains and losses on sales of marketable securities were not material for the years ended December 31, 2018, 2017, and 2016.

With respect to marketable securities, for the years ended December 31, 2018, 2017, and 2016, amounts reclassified from Accumulated other comprehensive (loss) income into Other income (expense), net were related to realized gains and losses on sales and the 2016 impairment charge on the equity security described above. The Company adopted ASU 2016-01 (see Note 1) during the first quarter of 2018; as a result, there were $41.9 million of net unrealized losses on equity securities recognized in Other income (expense), net for the year ended December 31, 2018. During the years ended December 31, 2017 and 2016, we recorded net unrealized gains of $14.7 million and net unrealized losses of $22.6 million, respectively, on equity securities in Other comprehensive (loss) income.

Table of Contents

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

5. Fair Value Measurements

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

As of December 31, 2018	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Available-for-sale debt securities:			
Corporate bonds	$2,718.4	—	$ 2,718.4
U.S. government and government agency obligations	109.4	—	109.4
Sovereign bonds	7.6	—	7.6
Commercial paper	113.8	—	113.8
Certificates of deposit	60.0	—	60.0
Equity securities (unrestricted)	43.6	$43.6	—
Equity securities (restricted)	44.4	—	44.4
	$3,097.2	$43.6	$ 3,053.6
As of December 31, 2017			
Available-for-sale debt securities:			
Corporate bonds	$1,712.5	—	$ 1,712.5
U.S. government and government agency obligations	185.5	—	185.5
Municipal and sovereign bonds	4.6	—	4.6
Commercial paper	107.0	—	107.0
Certificates of deposit	11.0	—	11.0
Equity securities (unrestricted)	62.7	$62.7	—
	$2,083.3	$62.7	$ 2,020.6

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 2018, 2017, and 2016.

The Company held certain restricted equity securities as of December 31, 2018, which are subject to transfer restrictions until 2020.

The fair value of interest rate swap and interest rate cap contracts, which were recorded within Other noncurrent assets, was not material as of December 31, 2018 and 2017, respectively (see Note 6). The fair value of these contracts was determined based on Level 2 inputs, using significant inputs that are observable either directly or indirectly,

including London Interbank Offered Rate ("LIBOR") and interest rate swap rates.

As of December 31, 2018 and 2017, the Company had $45.5 million and $37.5 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded at cost within Other noncurrent assets.

6. Derivative Instruments and Hedging Activities

The Company is exposed to market fluctuations in interest rates, including those in connection with its March 2017 lease of laboratory and office facilities in Tarrytown, New York (see Note 12). Commencing in the second quarter of 2017, the Company

Table of Contents

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

entered into interest rate swap and interest rate cap agreements to manage a portion of such interest rate risk; no new agreements of this nature were entered into during the year ended December 31, 2018. All of the Company's derivative instruments are utilized for risk management purposes, and are not used for trading or speculative purposes. The Company's derivative instruments are designated as cash flow hedges for accounting purposes. Since the specific terms of the derivative instruments match those of the item being hedged, the derivative instruments are deemed to be highly effective in offsetting the changes in cash flows of the hedged item. As such, changes in the fair value of these derivatives are recorded in accumulated other comprehensive income (loss) until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. The Company would record any gain or loss related to the ineffectiveness directly to earnings.

The Company assesses, both at inception and on an ongoing basis, whether derivatives used continue to be highly effective in offsetting changes in cash flows of the hedged items. The Company does not exclude any portion of the cash flow hedge contracts from the assessment of hedge effectiveness. If and when a derivative is no longer expected to be highly effective, hedge accounting would be discontinued.

The following table summarizes the notional amounts of the Company's outstanding interest rate swap and cap agreements:

	As of December 31, 2018	2017
Interest rate swap contracts	$75.0	$75.0
Interest rate cap contracts	$75.0	$75.0

As it relates to cash flow hedges, for the years ended December 31, 2018 and 2017, amounts of gains and losses recognized in Other comprehensive income (loss), and amounts reclassified from Accumulated other comprehensive (loss) income into Interest expense were not material. As of December 31, 2018, the amounts expected to be reclassified out of Accumulated other comprehensive (loss) income into Interest expense over the next 12 months are not expected to be material. There was no ineffective portion of the derivative instruments for the years ended December 31, 2018 and 2017, respectively.

7. Inventories

Inventories consist of the following:

	As of December 31, 2018	2017
Raw materials	$226.8	$190.0
Work-in-process	571.1	302.0
Finished goods	24.4	21.8
Deferred costs	328.9	212.3
	$1,151.2	$726.1

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).

Table of Contents

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

8. Property, Plant, and Equipment

Property, plant, and equipment consists of the following:

	As of December 31,	
	2018	2017
Land	$199.0	$192.8
Building and improvements	1,507.2	1,441.6
Leasehold improvements	97.0	102.6
Construction-in-progress	469.6	408.9
Laboratory and other equipment	773.7	599.1
Furniture, computer and office equipment, and other	258.0	179.9
	3,304.5	2,924.9
Less, accumulated depreciation and amortization	(728.7)	(566.3)
	$2,575.8	$2,358.6

As of December 31, 2018 and 2017, $1,813.8 million and $1,692.9 million, respectively, of the Company's net property, plant, and equipment was located in the United States and $762.0 million and $665.7 million, respectively, was located in Europe (primarily in Ireland).

Depreciation and amortization expense (including as it relates to capital and facility leases) on property, plant, and equipment amounted to $144.1 million, $142.2 million, and $104.7 million for the years ended December 31, 2018, 2017, and 2016, respectively.

Property, plant, and equipment, at cost, as of December 31, 2018 and 2017 included $723.9 million and $724.1 million, respectively, of leased property under the Company's capital and facility leases at its Tarrytown, New York facility. See Note 12. Accumulated amortization related to these assets amounted to $61.7 million and $47.9 million as of December 31, 2018 and 2017, respectively.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2018	2017
Accrued payroll and related costs	$261.8	$191.8
Accrued clinical trial expense	142.2	120.9
Accrued sales-related charges, deductions, and royalties	182.7	194.5
Income taxes payable	20.8	0.2
Other accrued expenses and liabilities	164.6	129.8
	$772.1	$637.2

Table of Contents

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

10. Deferred Revenue

Deferred revenue consists of the following:

	As of December 31,	
	2018	2017
Current portion:		
Received or receivable from Sanofi (see Note 3a)	$246.7	$177.7
Received or receivable from Bayer (see Note 3b)	44.4	39.0
Received or receivable from Teva (see Note 3c)	92.5	43.5
Other	68.9	59.9
	$452.5	$320.1
Long-term portion:		
Received or receivable from Sanofi (see Note 3a)	$279.3	$379.9
Received or receivable from Bayer (see Note 3b)	45.1	29.7
Received or receivable from Teva (see Note 3c)	102.0	153.9
Other	37.8	65.7
	$464.2	$629.2

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, and the Notes 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 $84.02 per share. In connection with the offering of the Notes, 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.

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.

Total interest expense associated with the Notes, net of capitalized interest as applicable, was not material in 2016.

Warrant Transactions

During 2015 and 2016, the Company entered into amendment agreements with warrant holders whereby the parties agreed to reduce a portion of 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. As a result of the warrant holders closing out a portion of their hedge positions, the Company paid a total of $242.2 million in 2016 to reduce the number of warrants held by such warrant holders.

Table of Contents

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

In addition, during 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 2016, and, as a result, no warrants remained outstanding as of December 31, 2016.

b. Credit Facility

In December 2018, 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"), and contemporaneously terminated our then-existing credit agreement (the "Prior Credit Agreement"). The Credit Agreement was entered into on terms substantially similar to those of the Prior Credit Agreement. No borrowings were outstanding under the Prior Credit Agreement at the time of its termination.

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 $50.0 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 December 2023, 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, 2018.

The Credit Agreement contains financial and operating covenants. The Company was in compliance with all covenants of the Credit Facility as of December 31, 2018.

12. Commitments and Contingencies

See Note 17 for disclosures related to legal contingencies.

a. Leases

The Company leases laboratory and office facilities in Tarrytown, New York (the "Tarrytown Leases"). Prior to December 30, 2016, certain of the premises under the Tarrytown Leases had been accounted for as operating leases, while for certain other buildings the Company leased, the Company was deemed, in substance, to be the owner of the landlord's buildings (collectively, the "Build-to-Suit Buildings") in accordance with the application of FASB authoritative guidance. In 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. The Company occupied a significant portion of the Facility, with the remaining rentable area 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. In March 2017, the Company also entered into a Participation Agreement with Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively, the "Participants"). The Participation Agreement provided for lease financing in connection with the acquisition by BAL of the Facility and the Company's lease of the Facility from BAL. On March 3, 2017, the right to take title to the Facility under the Purchase Agreement was assigned by the Company to BAL, and the Participants advanced $720.0 million, which was used by BAL to finance the purchase price for the Facility and to reimburse the Company for the $57.0 million payment made to BMR in December 2016. The $57.0 million reimbursement was recorded by the Company in March 2017 as an increase to capital and facility lease obligations in amounts equal to those initially recorded as reductions upon making such payment to BMR in December 2016.

In March 2017, the Company entered into a lease agreement (the "Lease") with BAL, pursuant to which the Company has leased the Facility from BAL for a five-year term. As a result of entering into the Lease, certain parts of the

Facility became subleased from the Company by existing third-party tenants. The Lease requires the Company to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. The Company is also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month LIBOR, plus an applicable margin that varies with the Company's debt rating and total leverage ratio.

Table of Contents

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

The Participation Agreement and the Lease include an option for the Company to elect to extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. The Company also has the option prior to the end of the term of the Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Participation Agreement, all accrued and unpaid interest and yield thereon, and all other outstanding amounts under the Participation Agreement, the Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL. The advances under the Participation Agreement mature, and all amounts outstanding thereunder will become due and payable in full at the end of the term of the Lease.

As a result of entering into the Lease, the premises that were classified as a capital lease as of December 31, 2016 were reassessed. The Company has the option to purchase the Facility (under terms that made it reasonably assured to be exercised), and as a result, the Company is deemed to have continuing involvement in such premises. Accordingly, these premises continue to be classified as a capital lease, with the related property, plant, and equipment and capital lease liability remaining on the Company's Consolidated Balance Sheet. In addition, upon entering into the Lease, the Company began to lease space occupied by third-party tenants. The lease of such premises is also classified as a capital lease. The execution of the Lease did not impact the balance sheet classification for the Build-to-Suit Buildings. However, in 2017, the Company recorded a $30.1 million loss on extinguishment of debt associated with the Build-to-Suit Buildings. In the aggregate, the Company had $720.0 million of capital and facility lease obligations upon execution of the Lease for the Facility.

The Participation Agreement and the Lease contain financial and operating covenants, which are substantially similar to the covenants set forth in the Company's credit facility (see Note 11). The Company was in compliance with all covenants of the Participation Agreement and the Lease as of December 31, 2018.

Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under existing operating leases, as of December 31, 2018, are as follows:

	Facilities	Equipment	Total
2019	$ 4.2	$ 6.2	$10.4
2020	3.6	0.2	3.8
2021	3.3	0.1	3.4
2022	2.2	—	2.2
2023	1.5	—	1.5
Thereafter	4.1	—	4.1
	$ 18.9	$ 6.5	$25.4

Rent expense under operating leases was:

Year Ended December 31,	Facilities	Equipment	Total
2018	$ 3.7	$ 1.2	$4.9
2017	$ 3.1	$ 1.2	$4.3
2016	$ 15.9	$ 0.9	$16.8

Capital and Facility Lease Obligations

In 2018, 2017, and 2016, the Company recognized $21.5 million, $19.5 million, and $5.4 million, respectively, of interest expense in connection with the Company's capital and facility lease obligations.

Table of Contents

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

As of December 31, 2018, the estimated future minimum noncancelable commitments under the Company's capital and facility lease obligations, excluding the purchase price the Company would be obligated to pay if the Company were to exercise its option to purchase the Facility (as described above), are as follows:

	Capital and Facility Lease Obligations
2019	$ 26.4
2020	28.4
2021	27.9
2022	7.0
2023	—
Thereafter	—
	$ 89.7

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, universities, and other organizations. 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, we have in-license patent and/or technology agreements which contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.5% to 11.5%, 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 for a more detailed description of collaboration agreements.

The Company and Genentech, a member of the Roche Group, entered into a Non-Exclusive License and Partial Settlement Agreement, as amended (the "Genentech Agreement"), that covered making, using, and selling EYLEA for the prevention of human eye diseases and disorders, and ended the litigation relating to those matters. Pursuant to the 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 Genentech Agreement obligated the Company to make payments to Genentech based on worldwide sales of EYLEA through 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. All payments to Genentech under the 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.

For the years ended December 31, 2018, 2017, and 2016, the Company recorded royalty expense of $36.7 million, $30.8 million, and $125.3 million, respectively, based on product sales of commercial products under various licensing agreements (including, in 2016, the Genentech Agreement 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, 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, with the Company. Under the terms of the amended and restated investor agreement, Sanofi has three demand rights to require the Company to use

Table of Contents

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

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 December 20, 2020 (subject to the limited waiver described below). 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.

As described in Note 3, effective January 7, 2018, the Company and Sanofi entered into a Letter Agreement, which, among other things, has amended certain provisions of the amended and restated investor agreement. Pursuant to the Letter Agreement, the Company has granted Sanofi a limited waiver of the lock-up obligations under the investor agreement to allow Sanofi to sell up to an aggregate of 1,400,000 shares (of which 1,173,847 shares remain available to be sold as of December 31, 2018) of the Company's Common Stock held by Sanofi for the quarterly periods through September 30, 2020.

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, 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. Subject to certain exceptions, the Company is required to use its reasonable efforts (including recommending that its shareholders vote in favor) to cause the election of this designee at the Company's annual shareholder meetings for so long as (other than during the term of the Letter Agreement) Sanofi maintains a specified equity interest in the Company.

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 (which, in the case of the PDGFR-beta license and collaboration agreement, occurred on July 31, 2017, and, in the case of the Ang2 agreement, occurred on November 1, 2018) 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 or

(ii) other specified events.

Table of Contents

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

14. Long-Term Incentive Plans

The Company has used long-term incentive plans for the purpose of granting equity awards to employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors (collectively, "Participants"). The Participants may receive awards as determined by a committee of independent members of the Company's board of directors or, to the extent authorized by such committee with respect to certain Participants, a duly authorized employee (collectively, the "Committee"). The incentive plan currently used by the Company is the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Amended and Restated 2014 Incentive Plan"). It was adopted in 2017 and the Company registered an additional 12,000,000 shares of Common Stock for issuance thereunder. As of the shareholder approval date, the Amended and Restated 2014 Incentive Plan provided for the issuance of up to 18,559,431 shares of Common Stock in respect of awards. In addition, upon expiration, forfeiture, surrender, exchange, cancellation, or termination of any award previously granted under the Amended and Restated 2014 Incentive Plan, the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Original 2014 Incentive Plan"), or the Second Amended and Restated 2000 Long-Term Incentive Plan (the predecessor to the Original 2014 Incentive Plan), any shares subject to such award are added to the pool of shares available for grant under the Amended and Restated 2014 Incentive Plan.

The awards that may be made under the Amended and Restated 2014 Incentive Plan include: (a) incentive stock options and nonqualified stock options, (b) shares of restricted stock, (c) shares of phantom stock (also referred to as restricted stock units), and (d) other awards.

Stock option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee, with exercise prices that are equal to or greater than the average of the high and low market prices of the Company's Common Stock on the date of grant (the "Market Price"). 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. The maximum term of options that have been awarded under the 2000 Incentive Plan, the Original 2014 Incentive Plan, and the Amended and Restated 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.

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.

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 Incentive Plans.

As of December 31, 2018, there were 12,115,845 shares available for future grants under the Amended and Restated 2014 Incentive Plan. No additional awards may be made under the 2000 Incentive Plan or the Original 2014 Incentive Plan.

Table of Contents

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

a. Stock Options

Transactions involving stock option awards during 2018 under the Company's Incentive Plans are summarized in the table below.

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Intrinsic Value
Outstanding as of December 31, 2017	26,205,373	$ 295.98		
2018: Granted	4,665,320	$ 378.51		
Forfeited	(668,550)	$ 422.56		
Expired	(205,030)	$ 467.40		
Exercised	(1,717,417)	$ 66.87		
Outstanding as of December 31, 2018	28,279,696	$ 319.28	6.43	$2,290.5
Vested and expected to vest as of December 31, 2018	27,192,461	$ 316.51	6.32	$2,289.1
Exercisable as of December 31, 2018	17,893,976	$ 275.10	4.98	$2,276.2

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 2018, 2017, and 2016 was $510.6 million, $735.6 million, and $550.4 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

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, 2018, 2017, and 2016. 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
2018:			
Exercise price equal to Market Price	4,665,320	$ 378.51	$ 114.39
2017:			
Exercise price equal to Market Price	4,235,015	$ 383.56	$ 118.70
2016:			
Exercise price equal to Market Price	4,201,978	$ 386.44	$ 126.68

For the years ended December 31, 2018, 2017, and 2016, the Company recognized $421.8 million, $492.8 million, and $546.0 million, respectively, of non-cash stock-based compensation expense related to stock option awards (net of

amounts capitalized to inventory of $17.1 million, $16.8 million, and $14.6 million, respectively). As of December 31, 2018, there was $702.6 million of stock-based compensation cost related to outstanding 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.

Table of Contents

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

Fair Value Assumptions:
The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2018, 2017, and 2016.

	2018	2017	2016
Expected volatility	29 %	31 %	34 %
Expected lives from grant date	4.9 years	5.1 years	5.1 years
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rate	2.69 %	2.16 %	1.84 %

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.

b. Restricted Stock Awards and Restricted Stock Units

A summary of the Company's activity related to restricted stock awards and restricted stock units (collectively, "restricted stock") during 2018 is summarized below:

	Number of Shares/Units	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2017	106,260	$ 404.72
2018: Granted	380,980	$ 381.21
Vested	(6,090)	$ 276.46
Forfeited/Cancelled	(8,520)	$ 478.19
Balance as of December 31, 2018	472,630	$ 386.10

The Company recognized non-cash stock-based compensation expense from restricted stock of $5.6 million, $14.5 million, and $13.9 million in 2018, 2017, and 2016, respectively (net of amounts capitalized to inventory, which were not material for each of the three years). As of December 31, 2018, there was $124.4 million of stock-based compensation cost related to unvested restricted stock which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 4.6 years.

15. Employee Savings Plans

The Company maintains the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan, as amended and restated (the "Savings Plan"). The terms of the Savings Plan 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 $27.0 million, $19.6 million, and $17.7 million of Contribution expense in 2018, 2017, and 2016, respectively.

The Company also maintains 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). Contributions to the Ireland Plan are comprised of two components: (i) a minimum mandatory employee and employer contribution rate, and (ii) a matching feature, whereby the Company will match employee contributions up to a certain percentage. Employees can make additional voluntary contributions to the Ireland Plan. Expenses recognized by the Company related to contributions to the Ireland Plan were not material during 2018, 2017, and

2016.

F- 37

Table of Contents

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unless otherwise noted, dollars in millions, 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,		
	2018	2017	2016
United States	$2,151.7	$1,964.7	$1,650.9
Foreign	401.8	113.8	(321.1)
	$2,553.5	$2,078.5	$1,329.8

Components of income tax expense consist of the following:

	Year Ended December 31,		
	2018	2017	2016
Current:			
Federal	$223.7	$560.3	$787.0
State	4.8	(4.1)	8.8
Foreign	20.6	4.8	(1.4)
Total current tax expense	249.1	561.0	794.4
Deferred:			
Federal	687.6	317.1	(377.4)
State	(1.9)	(1.3)	13.4
Foreign	(825.7)	3.2	3.9
Total deferred tax (benefit) expense	(140.0)	319.0	(360.1)
	$109.1	$880.0	$434.3

Table of Contents

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

On December 22, 2017, the bill known as the "Tax Cuts and Jobs Act" (the "Act") was signed into law. The Act, which became effective with respect to most of its provisions as of January 1, 2018, significantly revised U.S. corporate income tax laws by, among other things, reducing the U.S. federal corporate income tax rate from 35% to 21%, changing the taxation of foreign earnings (including taxation of certain global intangible low-taxed income ("GILTI")), allowing for a foreign-derived intangible income deduction and immediate expensing for qualified assets, repealing the deduction for domestic manufacturing, and imposing further limitations on the deductibility of executive compensation. As a result of the Act being signed into law, the Company recognized a provisional charge of $326.2 million in the fourth quarter of 2017 related to the re-measurement of its U.S. net deferred tax assets at the lower enacted corporate tax rate. The provisional charge recorded in the fourth quarter of 2017 was an estimate, and the measurement of deferred tax assets was subject to further analysis, such as developing interpretations and clarifications of the provisions of the Act. During 2018, we recorded an income tax benefit of $68.0 million as an adjustment to the provisional amount recorded as of December 31, 2017, which was partly attributable to our election to record deferred tax assets and liabilities for expected amounts of GILTI inclusions. Our assessment of the re-measurement of U.S. net deferred tax assets at the lower enacted corporate tax rate is now complete.

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,		
	2018	2017	2016
U.S. federal statutory tax rate	21.0 %	35.0 %	35.0 %
Impact of change in U.S. corporate tax rate (the Act)	(2.7)	15.7	—
Sale of non-inventory related assets between foreign subsidiaries	(6.3)	—	—
Stock-based compensation	(2.5)	(9.0)	(10.9)
Taxation of non-U.S. operations	(1.9)	0.7	8.8
Income tax credits	(2.6)	(1.3)	(1.2)
Non-deductible Branded Prescription Drug Fee	0.6	1.7	1.9
Foreign-derived intangible income deduction	(1.0)	—	—
Domestic production activities deduction	—	(2.6)	(2.8)
State and local income taxes	0.1	0.1	1.3
Other permanent differences	(0.4)	2.0	0.6
Effective income tax rate	4.3 %	42.3 %	32.7 %

In 2018, the difference between the U.S. federal statutory rate of 21% and the Company's effective tax rate of 4.3% was primarily attributable to the impact of the Company's sale of non-inventory related assets between foreign subsidiaries (including the associated impact of global intangible low-taxed income), as well as the federal tax credit for research activities, stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and the tax benefit associated with tax planning in connection with the Act. In 2017, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 42.3% was primarily attributable to the negative impact of the charge related to the re-measurement of the Company's U.S. net deferred tax assets upon the enactment of the Act (see above), partly offset by the tax benefit associated with stock-based compensation. 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, partly offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate.

Table of Contents

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unless otherwise noted, dollars in millions, 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,	
	2018	2017
Deferred tax assets:		
Deferred compensation	$458.2	$391.0
Fixed assets and intangible assets	107.8	—
Deferred revenue	20.2	102.4
Accrued expenses	53.3	38.3
Other	33.3	26.5
	672.8	558.2
Valuation allowance	—	(4.2)
Total deferred tax assets	672.8	554.0
Deferred tax liabilities:		
Fixed assets and intangible assets	—	(44.6)
Other	(2.7)	(3.1)
Total deferred tax liabilities	(2.7)	(47.7)
Net deferred tax assets	$670.1	$506.3

The Company's 2013 through 2017 federal income tax returns remain open to examination by the IRS. The Company's 2013 and 2015 federal income tax returns are currently under audit by the IRS. In general, the Company's state income tax returns from 2015 to 2017 remain open to examination. 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 $189.5 million, $146.2 million, and $107.2 million as of December 31, 2018, 2017, and 2016, respectively.

	2018	2017	2016
Balance as of January 1	$146.2	$117.2	$116.6
Gross increases related to current year tax positions	51.4	49.0	45.6
Gross increases (decreases) related to prior year tax positions	5.6	(5.6)	(42.3)
Gross decrease due to settlements, recapture, filed returns, and lapse of statutes of limitation	(13.7)	(14.4)	(2.7)
Balance as of December 31	$189.5	$146.2	$117.2

In 2018, 2017 and 2016, the increases in unrecognized tax benefits primarily related to the Company's calculation of certain tax credits and other items related to the Company's international operations. In 2018, there was a decrease in unrecognized tax benefits related to a settlement of the audit of the 2012 U.S. federal tax return and a lapse in the 2014 federal statute of limitations. In 2017 and 2016, there was a decrease in unrecognized tax benefits related to a settlement of a disputed state tax matter. In 2018, 2017, and 2016, accrued interest related to unrecognized tax benefits recorded by the Company was not material. The Company

Table of Contents

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

does not believe that it is reasonably possible that the resolution of tax exposures within the next twelve months will have a material impact on its unrecognized tax benefits as of December 31, 2018.

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. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Unless otherwise noted below, the Company is unable to predict the outcome, or estimate a range of possible loss or possible gain, of the respective proceedings. 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).

On September 25, 2013, the Company 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. The hearing for the Company's appeal and Kymab's cross-appeal was held on October 17–20, 2017. On March 28, 2018, the Court of Appeal (Civil Division of England and Wales) reversed the English High Court's decision and held that the '287 Patent and '163 Patent are both valid and infringed by Kymab. On June 5, 2018, the Court of Appeal issued a final order, which enjoins Kymab from infringing the '287 Patent and '163 Patent (subject to certain exceptions) and requires Kymab to destroy or deliver to a third party all products and antibodies and cells engineered to produce antibodies which infringe the '287 Patent and '163 Patent (subject to certain exceptions). On November 29, 2018, the Supreme Court of the United Kingdom granted Kymab's application for permission to appeal the order made by the Court of Appeal. The provisions of the final order of the Court of Appeal are stayed pending final determination of Kymab's appeal to the Supreme Court of the United Kingdom. The Company has also been awarded a portion of the legal fees incurred by it in connection with the proceedings in the English High Court of Justice and the Court of Appeal described above.

On March 11, 2014, the Company commenced '287 Patent infringement litigation and '018 Patent infringement litigation against Merus N.V., a company based in Utrecht, The Netherlands, in the District Court of The Hague and the United States District Court for the Southern District of New York, respectively. On November 21, 2014, the United States District Court for the Southern District of New York issued its Opinion and Order on Claim Construction in the '018 Patent infringement litigation, in which it held the '018 Patent invalid and not infringed. On November 2, 2015, the United States District Court for the Southern District of New York issued an opinion and order finding that the '018 Patent was procured by inequitable conduct, thus rendering it unenforceable. On July 27, 2017,

the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") affirmed the District Court's decision regarding inequitable conduct without deciding the issues of validity and infringement; and, on December 26, 2017, the Federal Circuit denied the Company's petition for panel rehearing and rehearing en banc. On October 1, 2018, the United States Supreme Court denied the Company's petition for a writ of certiorari. On December 20, 2018, the Company settled the '018 Patent infringement litigation as well as the '287 Patent infringement litigation in the Netherlands and all administrative proceedings between Merus and the Company pertaining to certain antibody generation platforms of each company (including the proceedings relating to Merus discussed in the paragraph below). As part of the settlement, both parties have signed a global patent cross-license agreement, Merus agreed to dismiss its action for legal fees, and the Company purchased 600,000 common shares of Merus for an aggregate purchase price of $15.0 million.

Table of Contents

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

On July 8 and July 13, 2016, notices of opposition against the '163 Patent were filed in the European Patent Office (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. The Company's response to the oppositions was filed on December 30, 2016. Following an oral hearing before the Opposition Division of the EPO on February 5–7, 2018, the Opposition Division upheld the '163 Patent without amendments. Kymab, Merus, and Novo Nordisk each filed a notice of appeal of the Opposition Division's decision on February 9, 2018, May 25, 2018, and June 26, 2018, respectively.

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 commercial 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 (the "District Court") from March 8 to March 16, 2016. During the course of the trial, the District 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 District 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 District 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 allowed 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 Federal Circuit. On April 19, 2017, the District Court granted Amgen's motion to amend the judgment on an accounting of supplemental damages and enhancement of such damages if deemed appropriate, but deferred the order until after the Federal Circuit issued a decision on the appeal. Oral argument on the appeal was held on June 6, 2017. On October 5, 2017, the Federal Circuit reversed in part the District Court's decision, remanded for a new trial on the issues of written description and enablement, and, as discussed below, vacated the District Court's permanent injunction. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious. The Federal Circuit further concluded the Company and the Sanofi defendants were not entitled to judgment as a matter of law on the issues of written description and enablement on this record. On February 23, 2018, the Federal Circuit denied Amgen's petition for rehearing en banc, and on March 2, 2018 the Federal Circuit issued a mandate to transfer jurisdiction of the case back to the District Court. On July 23, 2018, Amgen filed a petition for a writ of certiorari with the United States Supreme Court. On January 7, 2019, the United States Supreme Court denied Amgen's petition for a writ of certiorari. On January 3, 2019, the District Court held oral argument on the Company and the Sanofi defendants' motion for judgment on the pleadings regarding Amgen's willful infringement claim. On January 18, 2019, the District Court entered an order (i) denying the Company and the Sanofi defendants' motion for summary judgment on validity, (ii) denying Amgen's motion for partial summary judgment on estoppel, and (iii) granting the Company and the Sanofi defendants' cross-motion for summary judgment on estoppel. A new jury trial is currently scheduled to begin on February 19, 2019.

On January 5, 2017, the District Court granted a permanent injunction prohibiting Regeneron and the Sanofi defendants from Commercializing Praluent in the United States but subsequently delayed its imposition until February 21, 2017. The Federal Circuit stayed the injunction pending appeal on February 8, 2017 and vacated it on October 5, 2017.

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 (the "Düsseldorf Regional Court"), seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its

Table of Contents

removal from distribution channels, and damages. On November 14, 2017, the Düsseldorf Regional Court issued a decision staying the infringement proceedings until a decision of the Opposition Division of the EPO concerning the pending opposition filed by the Company, Sanofi, and several other opponents against the '124 Patent (as discussed below). Following Amgen's request to reopen the proceedings in light of the issuance of the Preliminary Opinion (as defined below), the Düsseldorf Regional Court held an oral hearing on September 11, 2018 and ruled on December 10, 2018 that the infringement proceedings would be reopened, with the next oral hearing in the Düsseldorf Regional Court scheduled for April 30, 2019.

On July 12, 2018, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie S.A. filed an action in the Federal Patents Court (the "FPC") in Munich, Germany, seeking a compulsory license from Amgen based on the '124 Patent for the continued commercializing of Praluent in Germany. This compulsory license action included a request for a provisional compulsory license. The FPC held an oral hearing on September 6, 2018 in the provisional compulsory license proceedings and denied Sanofi's request for the provisional compulsory license. On January 16, 2019, the Sanofi parties appealed the FPC's decision in the provisional compulsory license proceedings. The compulsory license proceedings are continuing.

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., Sanofi Winthrop Industrie, and Sanofi Chimie (subsequently added as a defendant). 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. On April 10, 2017, the Company and the Sanofi parties filed briefs seeking invalidation of certain of the claims of the '124 Patent, and Amgen filed a response on July 28, 2017. Oral hearing on this infringement lawsuit (originally scheduled for February 12, 2019) has yet to be scheduled.

The '124 Patent is also subject to opposition proceedings in the EPO seeking to invalidate certain of its claims, which were initiated by Sanofi on February 24, 2016 and, separately, by the Company, Sanofi, and several other opponents on November 24, 2016. On December 13, 2017, the Opposition Division of the EPO issued a preliminary, non-binding opinion (the "Preliminary Opinion") regarding the validity of the '124 Patent, indicating that it currently considers the claims of a new request filed by Amgen in response to the opposition to satisfy the requirements for patentability. An oral hearing on the oppositions against the '124 Patent was held on November 28–30, 2018, at which the Opposition Division upheld the validity of the '124 Patent's claims in amended form. The Company and Sanofi filed notices of appeal to the Technical Board of Appeal of the EPO on November 30, 2018.

The Company has recorded an accrual for loss contingencies associated with the '124 Patent proceedings discussed above. The ultimate resolution of these proceedings is not expected to have a material impact on the Company’s financial statements.

On May 19, 2017, Amgen filed a lawsuit for infringement of Amgen's Japanese Patent Nos. 5,906,333 (the "'333 Patent") and 5,705,288 (the "'288 Patent") in the Tokyo District Court Civil Division (the "Tokyo District Court") against Sanofi K.K. Amgen's complaint alleges that manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab) in Japan (as well as importing Praluent (alirocumab) into Japan) infringe the '333 and '288 Patents. The complaint further seeks a permanent injunction, disposal of product, and court costs. The Company has not been named as a defendant in this litigation. On January 17, 2019, the Tokyo District Court upheld the validity of the '333 Patent and '288 Patent and ordered a permanent injunction against Sanofi K.K. to stop manufacturing, selling or otherwise transferring, and offering to sell or otherwise transfer Praluent (alirocumab)

in Japan (as well as importing Praluent (alirocumab) into Japan) and to dispose of all product. However, the Tokyo District Court stayed the enforcement of such injunction pending appeal to the Intellectual Property High Court of Japan (the "IPHC"). On January 30, 2019, Sanofi K.K. appealed the Tokyo District Court's decision in the infringement proceedings to the IPHC.

Proceedings Relating to Dupixent (dupilumab) Injection

On March 20, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation filed a lawsuit against Amgen and Immunex Corporation, a wholly owned subsidiary of Amgen, in the United States District Court for the District of Massachusetts seeking a declaratory judgment that the Company's and the other plaintiffs' Commercializing of Dupixent does not directly or indirectly infringe U.S. Patent No. 8,679,487 (the "'487 Patent") owned by Immunex Corporation relating to antibodies that bind the human interleukin-4 receptor. On May 1, 2017, the Company and the other plaintiffs filed a notice of voluntary dismissal of this action without prejudice.

Table of Contents

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

On March 23, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation initiated an inter partes review ("IPR") in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of the '487 Patent. On July 28 and 31, 2017, the same parties filed two additional IPR petitions in the USPTO seeking declarations of invalidity of the '487 Patent based on different grounds (the "Additional IPR Petitions"). On October 4, 2017, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a decision on the first IPR petition and declined to institute an IPR proceeding to review the validity of the '487 Patent. On February 15, 2018, the PTAB issued two decisions instituting the Company's and Sanofi's Additional IPR Petitions on all claims of the '487 Patent for which review had been requested. Oral hearings on the Additional IPR Petitions before the PTAB were held on November 14, 2018.

On April 5, 2017, Immunex Corporation filed a lawsuit against the Company, Sanofi, Sanofi-Aventis U.S. LLC, Genzyme Corporation, and Aventisub LLC in the United States District Court for the Central District of California seeking a judgment of patent infringement of the '487 Patent and a declaratory judgment of infringement of the '487 Patent, in each case by the Company's and the other defendants' Commercializing of Dupixent; monetary damages (together with interest); an order of willful infringement of the '487 Patent, which would allow the court in its discretion to award damages up to three times the amount assessed; costs and expenses of the lawsuit; and attorneys' fees. Immunex is not seeking an injunction in this proceeding at this time. On June 21, 2017, the court denied a motion to dismiss Immunex's complaint previously filed by the Company and the Sanofi parties. On June 28, 2017, the Company and the Sanofi parties filed an answer to Immunex's complaint and counterclaims against Immunex and Amgen (which was amended on October 31, 2017 to, among other things, add an inequitable conduct allegation), and Immunex and Amgen filed an answer to the counterclaims on July 28, 2017. A combined hearing on the construction of certain disputed claim terms of the '487 Patent and the Company and the Sanofi parties' motion for summary judgment on the issue of indefiniteness of the '487 Patent claims was held on July 12, 2018. On August 24, 2018, the court issued an order denying this motion and construed the disputed claim terms as proposed by Amgen. A jury trial has been scheduled to start on November 5, 2019.

On September 30, 2016, Sanofi initiated a revocation proceeding in the United Kingdom to invalidate the U.K. counterpart of European Patent No. 2,292,665 (the "'665 Patent"), another patent owned by Immunex relating to antibodies that bind the human interleukin-4 receptor. 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 EPO opposition proceedings initiated by the Company and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions occurred on November 20, 2017, at which the claims of the '665 Patent were found invalid and the patent was revoked. A final written decision of revocation of the '665 Patent was issued by the EPO on January 4, 2018. Immunex filed a notice of appeal of the EPO's decision on January 31, 2018. On September 20, 2017 and September 21, 2017, respectively, the Company and Sanofi initiated opposition proceedings in the EPO against Immunex's European Patent No. 2,990,420 (the "'420 Patent"), a divisional patent of the '665 Patent (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). An oral hearing before the EPO on the '420 Patent opposition proceedings has been scheduled for February 14–15, 2019. The original patent term of the Immunex patents is set to expire in 2021.

Proceedings Relating to EYLEA (aflibercept) Injection and ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion

On March 19, 2018, Novartis Vaccines and Diagnostics, Inc., Novartis Pharma AG, and Grifols Worldwide Operations Limited (collectively, the "Novartis Parties") filed a lawsuit against the Company in the United States District Court for the Southern District of New York, seeking a judgment of patent infringement of U.S. Patent No. 5,688,688 (the "'688 Patent") by the Company's manufacture of aflibercept (the active ingredient used in both EYLEA and ZALTRAP); monetary damages (together with interest) for a limited period prior to the '688 Patent expiration; an

order of willful infringement of the '688 Patent (dismissed on October 24, 2018); costs and expenses of the lawsuit; and attorneys' fees. The '688 Patent expired on November 18, 2014. The Novartis Parties are not seeking an injunction in these proceedings.

Table of Contents

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unless otherwise noted, dollars in millions, 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 then 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 Regeneron Pharmaceuticals, Inc. 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 June 28, 2017, the court dismissed the plaintiff's claims with respect to certain compensation awarded in 2013 but denied the defendants' motion to dismiss the other claims set forth in the complaint. On November 8, 2017, another alleged shareholder filed a second shareholder derivative complaint in the New York Supreme Court, naming the then 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, the Company's Chief Scientific Officer, and Regeneron as defendants. 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 2014, 2015, and 2016. 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 the imposition of meaningful limits on the amount of equity payable to the individual defendants; 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 December 4, 2017, the plaintiff in the second action moved to consolidate both actions, to be appointed lead plaintiff, and to have its counsel be appointed lead counsel in the proposed consolidated action. The court heard oral argument on March 7, 2018 and denied the motion. The parties in both the first derivative action and the second derivative action agreed to a schedule for document discovery and the filing of defendants' appeal of the court's June 28, 2017 decision, as well as a stay of all non-document discovery pending a decision on defendants' appeal. On March 19, 2018, the defendants appealed the court's June 28, 2017 decision to the Appellate Division of the Supreme Court, First Department. On April 19, 2018, the Appellate Division granted the second plaintiff's motion to intervene in this appeal. On October 9, 2018, the parties to both derivative actions filed with the court a stipulation of compromise and settlement of both derivative actions. The stipulation requires Regeneron to, among other things, impose specified limitations on certain director compensation for the five years starting in December 2018, implement certain corporate governance measures, and pay the agreed-upon amount of attorneys' fees and expenses. Following a hearing on December 3, 2018, the court entered final judgments in both the first derivative action and the second derivative action, approving the settlement. Pursuant to the Company's By-Laws and the New York Business Corporation Law, expenses in connection with the foregoing were advanced by the Company for the individual defendants.

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. On or about November 3, 2017, the Company received a second shareholder litigation demand upon the Company's board of directors made by another purported Regeneron shareholder, which was substantially similar to the December 15, 2015 shareholder litigation demand. The demands asserted that the then 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 demands requested 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. On December 20, 2017, the parties to the shareholder derivative action filed on December 30, 2015 entered into a stipulation with the second demanding shareholder. The stipulation provides that the purported shareholder will intervene as a plaintiff in the action, and that the purported shareholder's litigation demand will be withdrawn and deemed null and void. The stipulation was approved by the court on January 18, 2018. The first shareholder litigation demand has also since been withdrawn.

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.

Table of Contents

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unless otherwise noted, dollars in millions, 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,		
	2018	2017	2016
Net income - basic	$2,444.4	$1,198.5	$895.5
Effect of dilutive securities:			
Convertible senior notes - interest expense and amortization of discount and note issuance costs	—	—	0.4
Net income - diluted	$2,444.4	$1,198.5	$895.9
(Shares in millions)			
Weighted average shares - basic	107.9	106.3	104.7
Effect of dilutive securities:			
Stock options	6.9	9.1	10.2
Restricted stock	—	0.5	0.5
Warrants	—	—	0.9
Dilutive potential shares	6.9	9.6	11.6
Weighted average shares - diluted	114.8	115.9	116.3
Net income per share - basic	$22.65	$11.27	$8.55
Net income per share - diluted	$21.29	$10.34	$7.70

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 millions)	2018	2017	2016
Stock options	14.9	9.2	8.0

19. Statement of Cash Flows

The Company adopted ASU 2016-18, Statement of Cash Flows - Restricted Cash, during the first quarter of 2018, and the standard has been retrospectively applied to all periods presented. The following provides a reconciliation of cash, cash equivalents, and restricted cash to the total of the same such amounts shown in the Consolidated Statement of Cash Flows:

	December 31, 2018	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 1,467.7	$ 812.7	$ 535.2
Restricted cash included in Other noncurrent assets	12.5	12.5	12.5
Total cash, cash equivalents, and restricted cash shown in the Consolidated Statement of Cash Flows	$ 1,480.2	$ 825.2	$ 547.7

Table of Contents

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

Restricted cash consists of amounts held by financial institutions pursuant to contractual arrangements.
Supplemental disclosure of non-cash investing and financing activities
Included in accounts payable, accrued expenses, and other liabilities as of December 31, 2018, 2017, and 2016 were $54.5 million, $41.8 million, and $28.2 million, respectively, of accrued capital expenditures.
As described in Note 3, during 2018, we purchased (by issuing a credit towards the amount owed by Sanofi) 215,387 shares of our Common Stock from Sanofi to satisfy Sanofi's funding obligation related to Libtayo development costs, and recorded the cost of the shares received, or $75.8 million, as Treasury Stock.
The Company recognized additional capital and facility lease obligations of $201.2 million and $154.9 million during 2017 and 2016, respectively, in connection with the Company's Tarrytown Leases (see Note 12). No additional capital and facility lease obligations were recognized during 2018.
20. Unaudited Quarterly Results
Summarized quarterly financial data (unaudited) for the years ended December 31, 2018 and 2017 are set forth in the following tables.

	First Quarter Ended March 31, 2018[1]	Second Quarter Ended June 30, 2018	Third Quarter Ended September 30, 2018	Fourth Quarter Ended December 31, 2018[2][3]
Revenues	$1,511.5	$1,608.0	$ 1,663.5	$ 1,927.8
Net income	$478.0	$551.4	$ 594.7	$ 820.4
Net income per share - basic	$4.44	$5.12	$ 5.50	$ 7.58
Net income per share - diluted	$4.16	$4.82	$ 5.17	$ 7.15

	First Quarter Ended March 31, 2017	Second Quarter Ended June 30, 2017	Third Quarter Ended September 30, 2017	Fourth Quarter Ended December 31, 2017[4]
Revenues	$1,319.0	$1,470.1	$ 1,500.7	$ 1,582.4
Net income	$248.9	$387.7	$ 388.3	$ 173.5
Net income per share - basic	$2.36	$3.66	$ 3.64	$ 1.62
Net income per share - diluted	$2.16	$3.34	$ 3.32	$ 1.50

[1] In the first quarter of 2018, the Company adopted ASC 606 and ASU 2016-01. Prior period amounts have not been adjusted in connection with the adoption of these accounting standards. See Note 1.
[2] Includes impact of a cumulative catch-up adjustment recorded to revenue upon modification of the Amended IO Discovery Agreement. See Note 3.
[3] Includes tax impact of the sale of non-inventory related assets between foreign subsidiaries completed during the fourth quarter of 2018. See Note 16.
[4]As a result of the Act being signed into law on December 22, 2017, the Company recognized a charge of $326.2 million in the fourth quarter of 2017 related to the re-measurement of its U.S. net deferred tax assets at the

lower enacted corporate tax rate. See Note 16.