UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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, including 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	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**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 ☒ 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 ☒

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 ☒ 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 ☒ No ☐

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 ☒ 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 ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was approximately $32,929,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 28, 2019, 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, 2020:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,848,970
Common Stock, $.001 par value	108,170,839

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2020 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 76 to 81 of this filing.

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

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (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 products marketed by us and/or our collaborators (collectively, "Regeneron's Products") and our product candidates and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Libtayo® (cemiplimab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, and REGN1979; the likelihood and timing of achieving any of our anticipated clinical development milestones referenced in this report; unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 Regeneron's Products, including without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, fasinumab, evinacumab, REGN-EB3, garetosmab, pozelimab, and REGN1979; 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 Regeneron's Products (such as EYLEA, Dupixent, Libtayo, Praluent, and Kevzara), 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 Regeneron's Products and product candidates; competing drugs and product candidates that may be superior to Regeneron's Products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's 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 (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and product candidates; coverage and reimbursement determinations by third-party payors, 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 and other related proceedings relating to Dupixent and Praluent described further in Note 16 to our Consolidated Financial Statements included in this report), other litigation and other proceedings and governmental investigations relating to the Company and/or its operations (including without limitation those described in Note 16 to our Consolidated Financial Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition. 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, pain, infectious diseases, and rare diseases.

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.

Selected financial information is summarized as follows:

	Year Ended December 31,		
(In millions, except per share data)	**2019**	**2018**	**2017**
Revenues	$ 7,863.4	$ 6,710.8	$ 5,872.2
Net income	$ 2,115.8	$ 2,444.4	$ 1,198.5
Net income per share - diluted	$ 18.46	$ 21.29	$ 10.34

In December 2019, we and Sanofi announced our intent to restructure the antibody collaboration for Kevzara and Praluent; completion of the proposed arrangement is expected to be finalized in the first quarter of 2020. Refer to "Collaboration Agreements - *Collaborations with Sanofi - Antibody*" section below for further details.

Marketed Products

We currently have seven products that have received marketing approval, which are currently marketed by us, Bayer, and/or Sanofi:

Product	Disease Area[1]	Territory			
		U.S.	EU	Japan	ROW[6]
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	a			
Dupixent (dupilumab) Injection[3]	- Atopic dermatitis (in adults and adolescents)[7]	a	a	a	a
	- Asthma (in adults and adolescents)	a	a	a	a
	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	a	a		a
Libtayo (cemiplimab) Injection[3][4]	- Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	a	a		a
Praluent (alirocumab) Injection[3]	- LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD") (in adults)	a	a	a	a
	- Cardiovascular risk reduction in patients with established cardiovascular disease	a	a		a
Kevzara (sarilumab) Solution for Subcutaneous Injection[3]	- Rheumatoid arthritis ("RA") (in adults)	a	a	a	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[5]	- 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] Marketed as Libtayo (cemiplimab-rwlc) Injection in the United States

[5] 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

[6] Rest of world. Checkmark in this column indicates that the product has received marketing approval in at least one country outside of the United States, European Union (EU), or Japan

[7] Approval in Japan is for adults and adolescents 15 years of age and older

Net Product Sales of Regeneron-Discovered Products[1]	**Year Ended December 31,**								
(In millions)	**2019**			**2018**			**2017**		
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**	**U.S.**	**ROW**	**Total**
EYLEA[1]	$ 4,644.2	$ 2,897.4	$ 7,541.6	$ 4,076.7	$ 2,668.9	$ 6,745.6	$ 3,701.9	$ 2,226.9	$ 5,928.8
Libtayo[1]	175.7	18.1	193.8	14.8	—	14.8	—	—	—
ARCALYST	14.5	—	14.5	14.7	—	14.7	16.6	—	16.6
Net product sales recorded by Regeneron	$ 4,834.4			$ 4,106.2			$ 3,718.5		
Net product sales recorded by Sanofi[1]:									
Dupixent	$ 1,871.2	$ 444.4	$ 2,315.6	$ 776.3	$ 145.7	$ 922.0	$ 253.8	$ 2.7	$ 256.5
Praluent	$ 126.0	$ 162.7	$ 288.7	$ 181.3	$ 125.5	$ 306.8	$ 131.4	$ 63.3	$ 194.7
Kevzara	$ 129.0	$ 77.7	$ 206.7	$ 74.7	$ 21.9	$ 96.6	$ 11.6	$ 1.7	$ 13.3
ZALTRAP	$ 7.3	$ 101.1	$ 108.4	$ 9.0	$ 98.8	$ 107.8	$ 10.7	$ 73.1	$ 83.8

[1] Bayer records net product sales of EYLEA outside the U.S., and Sanofi records net product sales of Libtayo outside the U.S. and global net product sales of Dupixent, Praluent, Kevzara, and ZALTRAP. Refer to "Collaboration Agreements" section below for further details.

Programs in Clinical Development

All 22 of our product candidates in clinical development, including the five U.S. Food and Drug Administration ("FDA") approved products which we are investigating in additional indications, were discovered in our research laboratories and are summarized in the table below. We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*® technology platforms (refer to "Research and Development Technologies - *VelociSuite*" section below). We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

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, changes to drug pricing and reimbursement regulations and requirements, and changes in the competitive landscape affecting a product candidate. The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. Refer to Part I, 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]	2019 and 2020 Events to Date	Select Upcoming Milestones
Ophthalmology						
EYLEA		- High-dose formulation in wet AMD	- Retinopathy of prematurity ("ROP")[c]		- Approved by FDA for the treatment of diabetic retinopathy - Pre-filled syringe approved by FDA	- Initiate Phase 3 studies of a high-dose formulation of aflibercept in wet AMD and DME (mid-2020)
Immunology & Inflammatory Diseases						
Dupixent (dupilumab)[a] *Antibody to IL-4R alpha subunit*		- Grass allergy - Peanut allergy	- Atopic dermatitis in pediatrics (6 months–5 years of age) (Phase 2/3)[d] - Asthma in pediatrics (6–11 years of age) - Eosinophilic esophagitis ("EOE")[c] - Chronic obstructive pulmonary disease ("COPD") - Bullous pemphigoid (Phase 2/3)[c] - Chronic spontaneous urticaria - Prurigo nodularis	- Atopic dermatitis in pediatrics (6–11 years of age) (U.S. and EU)[d] - CRSwNP (Japan) - Auto-injector for 300 mg dose (U.S. and Japan)	- Approved by FDA and European Commission ("EC") for expanded atopic dermatitis indication in adolescent patients (12–17 years of age) - Reported that Phase 3 study in pediatric patients (6–11 years of age) with severe atopic dermatitis met its primary and secondary endpoints - Approved by EC for treatment of asthma in adults and adolescents - Approved by FDA and EC for CRSwNP - EU approval for 200 mg and 300 mg auto-injector - FDA issued Complete Response Letter ("CRL") on sBLA for 200 mg auto-injector - Completed Phase 2a trial in grass allergy	- FDA decision (target action date of May 26, 2020) on supplemental Biologics License Application ("sBLA") and EC decision (second half 2020) for expanded atopic dermatitis indication in pediatric patients (6–11 years of age) - Report results from Phase 3 study for atopic dermatitis in pediatric patients (6 months–5 years of age) (2022) - Report results from Phase 3 study for asthma in pediatric patients (6–11 years of age) (second half 2020) - Japan decision on application for CRSwNP (first half 2020) - FDA decision on application for 300 mg auto-injector (target action date of March 20, 2020) - Resubmit sBLA for 200 mg auto-injector (first half 2020) - Present results from Phase 2a trial in grass allergy at medical meeting (first half 2020)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2019 and 2020 Events to Date	Select Upcoming Milestones
						- Report results from Phase 2 study in peanut allergy (first half 2021) - Initiate Phase 3 study in pediatric patients with EOE (second half 2020) - Report results from Phase 2 portion of Phase 2/3 study in EOE (mid-2020) - Initiate Phase 3 studies in hand and foot atopic dermatitis and allergic bronchopulmonary aspergillosis ("ABPA") (first half 2020)
Kevzara (sarilumab)[a] *Antibody to IL-6R*		- Polyarticular-course juvenile idiopathic arthritis ("pcJIA") - Systemic juvenile idiopathic arthritis ("sJIA")	- Polymyalgia rheumatica ("PMR") - Giant cell arteritis ("GCA")			
REGN3500[a] *Antibody to IL-33. Studied as monotherapy and in combination with Dupixent.*		- Asthma - COPD - Atopic dermatitis			- Reported that Phase 2 study in asthma met its primary and key secondary endpoints - Sanofi reported that Phase 2 study in COPD demonstrated reduced exacerbations in the overall study population, but results were not statistically significant	- Report results from Phase 2 study in atopic dermatitis (second half 2020) - Initiate Phase 2b study in asthma (second half 2020)
REGN1908-1909[f] *Multi-antibody therapy to Feld1*		- Cat allergy				- Report results from Phase 2 study in cat allergic asthmatics (first half 2020)
REGN5713-5714-5715 *Antibody to Betv1*	- Birch allergy					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2019 and 2020 Events to Date	Select Upcoming Milestones
Oncology						
Libtayo (cemiplimab)[a][h] *Antibody to PD-1*	- Solid tumors and advanced hematologic malignancies	- Basal cell carcinoma ("BCC") (potentially pivotal study) - Metastatic or locally advanced CSCC[d] - Neoadjuvant CSCC	- First-line non-small cell lung cancer ("NSCLC") - Second-line cervical cancer[e] - Adjuvant CSCC		- Conditionally approved by EC for treatment of advanced CSCC - Independent data monitoring committee conducted an interim analysis for overall survival in a Phase 3 NSCLC trial, and recommended trial continue as planned	- Report results from potentially pivotal Phase 2 study in BCC (mid-2020) - Report results from Phase 3 study in cervical cancer (first half 2021) - Interim analysis of overall survival from Phase 3 NSCLC monotherapy study (2020)
REGN1979 *Bispecific antibody targeting CD20 and CD3*	- Certain B-cell malignancies[c]	- B-cell non-Hodgkin lymphoma ("B-NHL") (potentially pivotal study)			- Reported updated results from Phase 1 trial in B-cell malignancies - Continued to expand potentially pivotal Phase 2 program with different subtypes of NHL	- Report updated results from initial study in certain B-cell malignancies (2020) - Continue to expand potentially pivotal Phase 2 study (2020)
REGN5458[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma				- Reported positive preliminary results from Phase 1 trial in multiple myeloma	- Report updated results from initial study in multiple myeloma (2020)
REGN5459[a] *Bispecific antibody targeting BCMA and CD3*	- Multiple myeloma					
REGN4018[a] *Bispecific antibody targeting MUC16 and CD3*	- Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	- Prostate cancer					
REGN5093 *Bispecific antibody targeting two distinct MET epitopes*	- MET-altered advanced NSCLC					
REGN3767[f] *Antibody to LAG-3*	- Solid tumors and advanced hematologic malignancies					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2019 and 2020 Events to Date	Select Upcoming Milestones
Cardiovascular/Metabolic Diseases						
Praluent (alirocumab)[a] *Antibody to PCSK9*			- Homozygous familial hypercholesterolemia ("HoFH")[c] in adults and pediatrics - HeFH in pediatrics		- Approved by EC for a new indication to reduce cardiovascular risk in adults with established ASCVD - Approved by FDA for a new indication to reduce the risk of heart attack, stroke and unstable angina requiring hospitalization in adults with established CV disease - Approved by FDA for treatment of adults with primary hyperlipidemia (including HeFH) to reduce low-density lipoprotein cholesterol ("LDL-C")	- Report results from Phase 3 study in HoFH and submit sBLA (2020)
Evinacumab[f] (REGN1500) *Antibody to ANGPTL3*		- Refractory hypercholesterolemia (both HeFH and non-FH) - Severe hypertriglyceridemia	- HoFH[c][d]		- Reported positive top-line results from Phase 3 trial in HoFH	- Submit BLA and Marketing Authorization Application ("MAA") for HoFH (2020)
Pozelimab[f] (REGN3918) *Antibody to C5*		- Paroxysmal nocturnal hemoglobinuria ("PNH")[c]			- Reported positive top-line results from Phase 2 trial in PNH	- Initiate combination program with Alnylam's cemdisiran (second half 2020) - Initiate Phase 3 program in PNH (second half 2020)
Garetosmab[f] (REGN2477) *Antibody to Activin A*		- Fibrodysplasia ossificans progressiva ("FOP")[c][e] (potentially pivotal study)			- Reported results from Phase 2 study in FOP	- Discuss regulatory submission for FOP with regulatory authorities (first half 2020)
REGN4461[f] *Agonist antibody to leptin receptor ("LEPR")*		- Generalized lipodystrophy[e]				

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[i]	2019 and 2020 Events to Date	Select Upcoming Milestones
Pain						
Fasinumab[b][f] (REGN475) *Antibody to NGF*			- Osteoarthritis pain of the knee or hip[e]			- Report results from Phase 3 studies in osteoarthritis pain of the knee or hip (mid-2020)
REGN5069 *Antibody to GFRα3*		- Osteoarthritis pain of the knee[e]				- Report results from Phase 2 study in osteoarthritis pain of the knee (second half 2020)
Infectious Diseases						
REGN-EB3[f][g] (REGN3470-3471-3479) *Multi-antibody therapy to Ebola virus infection ("Ebola")*				- Ebola (U.S.)[c][d][j]	- Investigational trial in the Democratic Republic of Congo was stopped early based on data showing that REGN-EB3 was superior to ZMapp in preventing death	- Complete rolling BLA submission for Ebola (first half 2020)

Note 1: For purposes of the table above, a program is classified in Phase 1, 2, or 3 clinical development after recruiting for the corresponding study or studies has commenced

Note 2: We have discontinued further clinical development of REGN4659, an antibody to CTLA4, which was previously being studied in advanced NSCLC

[a] In collaboration with Sanofi

[b] In collaboration with Teva and Mitsubishi Tanabe Pharma

[c] 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 sales of the product candidate.

[g] 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] Information in this column relates to U.S., EU, and Japan regulatory submissions only

[j] Included as part of the Extension Phase of a trial coordinated by World Health Organization

Additional Information - Marketed Products Studied in Additional Indications and Product Candidates in Late-Stage Clinical Development

EYLEA

EYLEA is a soluble fusion protein that acts as a vascular endothelial growth factor ("VEGF") inhibitor, formulated as an injection for the eye. It is designed to block the growth of new blood vessels and decrease the ability of fluid to pass through blood vessels (vascular permeability) in the eye by blocking VEGF-A and PLGF, two growth factors involved in angiogenesis.

Dupixent (dupilumab)

Dupixent is a fully-human monoclonal antibody that inhibits the signaling pathway of IL-4 and IL-13. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma, and CRSwNP, as well as other immunological and inflammatory diseases.

Kevzara (sarilumab)

Kevzara is a fully-human monoclonal antibody that binds specifically to the IL-6 receptor and inhibits IL-6-mediated signaling. IL-6 is a signaling protein produced in increased quantities in patients with RA and has been associated with disease activity, joint destruction, and other systemic problems.

Libtayo (cemiplimab) and REGN1979

Regeneron is developing a diverse and comprehensive oncology portfolio, including Libtayo, which is being studied as monotherapy and in combination with other anti-cancer agents in various indications.

Libtayo is a fully-human monoclonal antibody targeting the immune checkpoint receptor PD-1. The PD-1/PD-L1 immune checkpoint pathway has emerged as a major mechanism by which cancers evade immune destruction. Libtayo is also being studied by other companies in combination with their proprietary assets.

REGN1979 is an investigational bispecific monoclonal antibody designed to bridge T-cells and tumor cells. It is designed to trigger tumor killing by binding to both a protein expressed on B-cell cancers (CD20) and a component of the T-cell receptor ("TCR") complex (CD3). At the tumor site, it activates T-cells by engaging their CD3 molecules and promotes T-cell mediated killing of the cancer cells.

Praluent (alirocumab)

Praluent is a fully-human monoclonal antibody that inhibits the binding of PCSK9 to the LDL receptor. Through inhibiting PCSK9, Praluent increases the number of available LDL receptors on the surface of liver cells to clear LDL, which lowers LDL cholesterol levels in the blood.

Evinacumab

Evinacumab is an investigational, fully-human monoclonal antibody that specifically binds to and blocks ANGPTL3. ANGPTL3 plays a key role in regulating plasma lipid levels, including triglycerides, LDL cholesterol, and HDL cholesterol, through inhibition of lipase enzymes (lipoprotein lipase and endothelial lipase).

Pozelimab

Pozelimab is an investigational, fully-human monoclonal antibody designed to block complement factor C5 and prevent the destruction of red blood cells that cause the symptoms of PNH and other diseases mediated by abnormal complement pathway activity. PNH is an ultra-rare, chronic, life-threatening disease where genetic mutations cause hemolysis, resulting in a range of symptoms including fatigue, shortness of breath, and blood clots. Pozelimab binds with high affinity to wild-type and variant human C5 and blocks its activity.

Garetosmab

Garetosmab is an investigational, fully-human monoclonal antibody that binds and neutralizes Activin A, which is required for the development of additional bone outside the normal skeleton in patients with the ultra-rare genetic disorder, FOP. The abnormal bone formation in soft tissue outside of the normal skeleton, a process known as heterotopic ossification, leads to loss of mobility and premature death in FOP patients. Garetosmab reduces the formation of heterotopic bone lesions by neutralizing the Activin A protein.

Fasinumab

Fasinumab is an investigational, fully-human monoclonal antibody that targets NGF, a protein that plays a central role in the regulation of pain signaling. NGF expression is elevated in many acute and chronic pain conditions and NGF blockade has demonstrated efficacy in clinical trials. Targeting NGF is a potential new way to manage pain without resorting to opioids.

REGN-EB3

REGN-EB3 is an investigational cocktail of three fully-human monoclonal antibodies that each bind to the Ebola virus at different points, which may serve to increase efficacy, reduce the development of viral sequences that lead to resistance, and potentially enable utility in future outbreaks as viruses continue to evolve. REGN-EB3 is being developed, tested, and manufactured through contracts awarded in 2015 and 2017 by BARDA, under the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services.

Other Programs

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

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, which 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*®, *VelociT*™, and other related technologies. The *VelocImmune* mouse platform is utilized to produce fully human antibodies. *VelocImmune* was generated by leveraging 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 CD3 bi-specific antibody, REGN1979, targets CD20. We are

exploring additional indications and applications for our bi-specific technologies, such as other CD3 bi-specific antibodies to MUC16 (REGN4018) and BCMA (REGN5458 and REGN5459), as well as a new class of CD28 co-stimulatory bi-specifics, including an antibody that targets PSMA (REGN5678).

The *VelociT* mouse extends our research and drug discovery capabilities into cell-mediated immunity and therapeutic TCRs for oncology and other indications. *VelociT* was developed by using our *VelociGene* technology to humanize genes encoding TCRa and TCRb variable sequences, CD4 and CD8 co-receptors, β2m, and class-I and -II major histocompatibility complexes. As a result, *VelociT* mice generate fully human TCRs, providing for customized modeling of T-cell function in different diseases and a powerful platform for the discovery of unique TCR-based therapies.

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 million in funding for Regeneron to sequence the UK Biobank's samples, which is performed at the RGC facility. Consortium members have a limited period of exclusive access to the sequencing data before the data are 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 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

Antibody

We are collaborating with Sanofi on the global development and commercialization of Dupixent, Praluent, Kevzara, and REGN3500 (the "Antibody Collaboration"). Under the terms of the Antibody License and Collaboration Agreement (the "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 obligated to reimburse Sanofi for 50% of worldwide development expenses that were fully funded by Sanofi and 30% of shared Phase 3 trial-related costs based on our share of collaboration profits from commercialization of collaboration products. However, we are only required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs.

In January 2018, we and Sanofi entered into a letter agreement (the "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 495,948 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-commercialize such products on a country-by-country basis. We have exercised our option to co-commercialize Dupixent, Praluent, and Kevzara in the United States, and have exercised our option to co-commercialize Dupixent in certain countries outside the United States. We currently anticipate commencing co-commercialization of Dupixent outside the United States at the end of 2020. 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 an aggregate of $250.0 million in milestone payments upon achievement of specified aggregate annual sales of antibodies (subject to this agreement) outside the United States on a rolling twelve-month basis. The Company will be entitled to receive the first sales milestone payment from Sanofi, in the amount of $50.0 million, when such sales outside the United States exceed $1.0 billion.

In December 2019, we and Sanofi announced our intent to restructure the Antibody Collaboration for Kevzara and Praluent and enter into a royalty-based arrangement. Under the proposed terms of the agreement, Sanofi is expected to gain sole global rights to Kevzara and sole rights to Praluent outside of the United States. Regeneron is expected to gain sole U.S. rights to Praluent. Under the proposed terms, each party will be solely responsible for funding development and commercialization expenses in their respective territories. In connection with the proposed agreement, the Company has eliminated certain commercialization activities and related headcount. The proposed agreement, which is expected to be finalized in the first quarter of 2020, will not impact the companies' existing collaboration relating to Dupixent and REGN3500.

Immuno-Oncology

We are collaborating with Sanofi on the development and commercialization of 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 (the "Amended IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement (the "IO License and Collaboration Agreement").

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 original 2015 Immuno-oncology Discovery and Development Agreement (the "2015 IO Discovery Agreement") to developing therapeutic bispecific 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 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 Amended IO Discovery Agreement from our share of profits from commercialized IO Collaboration products.

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when (i) clinical proof-of-concept is established, (ii) the applicable Program Costs Cap is reached, or (iii) 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, we 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 global commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) we 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.

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-commercialize 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 and co-commercializing 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 and commercialization expenses for Libtayo. Under the Letter Agreement, we have 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 373,880 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 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. Refer to the *"Antibody"* section above for a description of share transactions related to Dupilumab/REGN3500 Eligible Investments.

With regard to Libtayo, we lead commercialization activities in the United States, while Sanofi leads commercialization activities outside of the United States and the parties equally share profits from worldwide sales. Sanofi has exercised its option to co-commercialize 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.

Collaboration with Bayer

EYLEA outside the United States

Since 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 through 2021, and thereafter, the companies will share equally in profits and losses from the sales of EYLEA.

We are 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.

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

Collaboration with Teva

Fasinumab

In 2016, we entered into a collaboration agreement with Teva to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with Mitsubishi Tanabe Pharma Corporation ("MTPC"). In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment. 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, 2019, 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 Alnylam

In April 2019, we and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNAi therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. The collaboration is governed by a Master Collaboration Agreement (the "Master Agreement") (including the form of a License Agreement and a Co-Commercialization Collaboration Agreement). Under the terms of the Master Agreement, we made an up-front payment of $400.0 million to Alnylam. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200.0 million in clinical proof-of-principle milestones for eye or CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Commercialization Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more INDs (or their equivalent in certain other countries) for programs in the eye and CNS.

At the stage of designation of a lead candidate for CNS programs and liver programs, the parties have alternating rights to be a lead party for collaboration products. At the stage of designation of a lead candidate for eye programs, we have the sole right to take the product forward as a licensee. The lead party is required to take the program forward under the License Agreement structure unless the other party exercises its rights to opt-in to a Co-Commercialization Collaboration Agreement, in which case the lead party is required to take the program forward under the Co-Commercialization Collaboration Agreement structure. Alnylam does not have rights to opt-in to a Co-Commercialization Collaboration Agreement for eye programs.

Under a License Agreement, the lead party is designated as the licensee and has the right to develop and commercialize the collaboration product under such program. The licensee will be responsible for its own costs and expenses incurred in connection with the development and commercialization of the collaboration products under the License Agreement. The licensee will pay to the licensor certain development and/or commercialization milestone payments totaling up to $150.0 million for each collaboration product. In addition, following the first commercial sale of the applicable collaboration product under a License Agreement, the licensee is required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the licensor based on the aggregate annual net sales of the collaboration product, subject to customary reductions.

For CNS programs and liver programs, as soon as a party is designated as a lead party, the other company has rights to opt-in to a Co-Commercialization Collaboration Agreement as a participating party. Under a Co-Commercialization Collaboration Agreement, the party designated as the lead party has operational responsibility and final decision-making authority on development and commercialization of the program and the parties will split profits and share costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions. If a party exercises its co-funding opt-out right, the lead party will be required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the other party based on the aggregate annual net sales of the collaboration product and the timing of the exercise of the co-funding opt-out right, subject to customary reductions. If the non-lead party does not initially opt-in to a Co-Commercialization Collaboration Agreement, the lead party has the right to take the program forward under a License Agreement structure.

Under the collaboration, when we are the licensee under a License Agreement or the lead party under a Co-Commercialization Collaboration Agreement, Alnylam will be responsible for the manufacture and supply of the product to us for Phase 1 and Phase 2 clinical trials.

In connection with the collaboration, we and Alnylam also entered into a Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, we purchased 4,444,445 shares of Alnylam common stock for aggregate cash consideration of $400.0 million.

In August 2019, the parties entered into a Co-Commercialization Collaboration Agreement for a silencing RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic and a fully human monoclonal antibody targeting C5 being developed by us, with us as the licensee. The C5 siRNA Co-Commercialization Collaboration Agreement is consistent with the financial terms contained in the form of the existing Co-Commercialization Collaboration Agreement with Alnylam. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on our potential future net sales of the combination product only subject to customary reductions, as well as up to $325.0 million in commercial milestones.

Manufacturing

We currently manufacture bulk drug materials and products at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland. These facilities consist of owned and leased research, manufacturing, office, laboratory, and warehouse space. In addition, during 2020, we expect to continue the construction of a fill/finish facility in Rensselaer, New York.

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 bulk drug materials and products. In addition, we currently have approximately 130,000 liters of cell culture capacity at our Limerick facility which 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 materials and products.

Certain bulk drug materials and products 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, 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 work closely with our collaborators for co-developed products to create marketing plans and forecasts and to establish 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, inflammation, and cardiovascular. We have approximately 500 field-based employees in the United States.

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 the 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, 2019. On a combined basis, our product sales to these customers accounted for approximately 90% of our gross product revenue for the year ended December 31, 2019. 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 (refer to "Collaboration Agreements" section above for additional information).

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 or biotechnology 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.

Marketed Products

The table below provides an overview of the current competitive landscape for the key products marketed by us and/or our collaborators under our collaboration agreements with them in such products' currently approved indications. The table below is provided for illustrative purposes only and is not exhaustive. For additional information regarding the substantial competition these marketed products face, including potential future competition from product candidates in clinical development, 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 significant competition.*"

Marketed Product	Competitor Product	Competitor	Indication	Territory[1]
EYLEA	Lucentis® (ranibizumab)	Novartis AG and Genentech/Roche	Wet AMD, DME, macular edema following RVO (including CRVO and BRVO), diabetic retinopathy, mCNV, and ROP	Worldwide
	Avastin® (bevacizumab) (off-label and repackaged)	Genentech/Roche	Wet AMD, DME, and macular edema following RVO	Worldwide
	Beovu® (brolucizumab)	Novartis	Wet AMD	United States
	Ozurdex® (dexamethasone intravitreal implant)	Allergan, PLC	DME, RVO	Worldwide
	Iluvien® (fluocinolone acetonide intravitreal implant)	Alimera Sciences, Inc.	DME	Worldwide
	Conbercept	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	Wet AMD, mCNV	China
Dupixent	Eucrisa® (crisaborole)	Pfizer	Mild-to-moderate atopic dermatitis	United States
	Xolair® (omalizumab)	Roche/Novartis	Asthma	Worldwide
	Nucala® (mepolizumab)	GlaxoSmithKline ("GSK")	Asthma	Worldwide
	Cinqair® (reslizumab)	Teva	Asthma	United States, EU
	Fasenra® (benralizumab)	AstraZeneca	Asthma	Worldwide
Libtayo	Keytruda® (pembrolizumab)	Merck & Co., Inc.	Various cancers	Worldwide
	Opdivo® (nivolumab)	Bristol-Myers Squibb	Various cancers	Worldwide
	Tecentriq® (atezolizumab)	Roche	Various cancers	Worldwide
	Imfinzi® (durvalumab)	AstraZeneca	Various cancers	Worldwide
	Bavencio® (avelumab)	Pfizer/Merck KGaA	Various cancers	Worldwide
Praluent	Repatha® (evolocumab)	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
Kevzara	Actemra® (tocilizumab)	Genentech/Roche/ Chugai Pharmaceutical Co., Ltd.	Rheumatoid arthritis	Worldwide
	Orencia® (abatacept)	Bristol-Myers Squibb	Rheumatoid arthritis	Worldwide
	Xeljanz® (tofacitinib)	Pfizer	Rheumatoid arthritis	Worldwide
	Olumiant® (baricitinib)	Eli Lilly/Incyte	Rheumatoid arthritis	Worldwide
	Rinvoq® (upadacitinib)	AbbVie	Rheumatoid arthritis	Worldwide

[1] This table focuses primarily on the United States, EU, and Japan. "Worldwide" indicates that the relevant product is approved in at least the United States, EU, and Japan.

Antibodies in Development

Our antibody-based 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. 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 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 significant competition*."

Other Areas

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

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

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

Patents, Trademarks, and Trade Secrets

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 16 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.

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
		US	10,406,226	Method of Manufacturing	March 22, 2026
		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	March 28, 2031****
		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)**
Libtayo	cemiplimab	US	9,987,500	Composition of Matter	September 18, 2035
Praluent***	alirocumab	US	8,062,640	Composition of Matter	December 15, 2029
		US	10,023,654	Composition of Matter	December 15, 2029
		US	10,472,425	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	10,072,086	Formulation	September 19, 2031
		US	8,080,248	Methods of Treatment	June 1, 2027
		US	8,568,721	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

* 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 applicable dates indicated in parentheses.

*** See Note 16 to our Consolidated Financial Statements for information regarding the patent infringement proceedings relating to Dupixent and Praluent.

**** A patent term extension has been granted by the U.S. Patent and Trademark Office, extending the original patent term (October 2, 2027), insofar as it covers Dupixent, to March 28, 2031.

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 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 16 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 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 BLA for evaluation to determine whether the product 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 to 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 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 payors, including private payor 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 payors, 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 (the "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 consist of 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 (the "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.

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 implemented a new price reporting system during the first quarter of 2019, under which manufacturers are now required to report their 340B ceiling prices to HRSA on a quarterly basis. 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, if applicable, an additional discount. The additional discount applies if non-FAMP increases more than inflation (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 2020, 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 payors 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*."

In the United States, there are federal and state privacy laws that regulate specific categories of personal data. The information privacy laws address state and federal health information, consumer protection, and children's personal data. There are also data protection laws that govern data breach notification and information security. 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. 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. To the extent we collect California resident personal data for marketing activities, we are also subject to the California Consumer Privacy Act of 2018 (the "CCPA"). The CCPA became effective on January 1, 2020 and provides California residents with certain rights concerning the use of their personal data. The obligations to comply with the CCPA require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with the CCPA. Outside the United States, our clinical trial programs and research collaborations 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 and samples 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 promulgate national privacy laws that 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 personal information we collect from individuals, data brokers, or research institutions or obtain from clinical trials sponsored by us or our collaborators*."

In addition to the foregoing, our present business is, and our future business may 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 diseases. 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, 2019, we had approximately 8,100 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.

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. For purposes of this section, references to our products encompass products marketed by us and/or our collaborators under our collaboration agreements with them, unless otherwise stated or required by the context.

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, 2019 and 2018, EYLEA net sales in the United States represented 59% and 61% 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 degree of commercial success of our marketed products will continue to 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 payors, including Medicare and Medicaid in the United States and other government and private payors in the United States and foreign jurisdictions, as well as U.S. and foreign payor restrictions on eligible patient populations and the reimbursement process (including drug price control measures that may be introduced in the United States by various federal and state authorities);
- 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 existing and potential new competition for EYLEA (discussed further under "*The commercial success of our products and product candidates is subject to significant competition* - Marketed Products" below) and the willingness of retinal specialists and patients to start or continue treatment with EYLEA or to switch from another product to EYLEA;
- serious complications or side effects in connection with the use of our marketed products, as discussed 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 - *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;
- 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 Dupixent and Praluent (described further in Note 16 to our Consolidated Financial Statements included in this report), as well as 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 outcome of the pending government investigations described in Note 16 to our Consolidated Financial Statements included in this report;
- 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 price reporting and other disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescribing practices and payor coverage.

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

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 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.

Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales of our marketed products in the United States are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor 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 payors 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 payors cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payors more expensive for patients. Third-party payors 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 payors (such as Medicare and Medicaid in the United States) to reimburse the cost of our marketed products, we must maintain, among other things, our FDA registration and our National Drug Code, formulary approval by pharmacy benefits managers, and 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.

Government and other third-party payors (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, such as step therapy (*i.e.*, requiring the use of less costly medications before more costly medications are approved for coverage). 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 and policies 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 prior budget proposals (including the proposal for fiscal year 2020) contained

drug price control measures that may be subsequently rolled into the budget proposal for fiscal year 2021 and could be enacted during the 2021 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, since January 1, 2019, CMS has allowed Medicare Advantage ("MA") plans to use step therapy for Part B drugs (such as EYLEA). On October 25, 2018, President Trump announced that CMS was evaluating a 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 or international price index ("IPI") drug 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 proposed program, which is contemplated to initially cover fifty percent of Medicare Part B spending on separately payable Part B drugs (such as EYLEA), with the IPI-based price for each such drug to be phased in over a period of five years; notice of proposed rulemaking on this program is pending review by the Office of Management and Budget. In addition, in July 2019, President Trump indicated that his administration was considering an executive order to establish a "most favored nation" pricing plan. While the scope and details of this contemplated executive action (including whether and how its mechanism may differ from that of the proposed IPI drug pricing program discussed above) are not clear, this seems to signal that the U.S. administration will continue to seek new measures to constrain drug costs and Medicare payments for drugs. Similarly, various members of the current U.S. Congress and potential 2020 presidential candidates have indicated that lowering drug prices continues to be a legislative and political priority, and some have introduced proposals aimed at drug pricing. 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 price 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 payor 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.

The commercial success of our products and product candidates is subject to significant 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 larger pharmaceutical or biotechnology companies. There is significant actual and potential future competition for each of our marketed products.

EYLEA faces significant competition in the marketplace. For example, EYLEA competes in one or more of its approved indications with other VEGF inhibitors, including Novartis and Genentech/Roche's Lucentis and Novartis' Beovu. Ophthalmologists are also using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, bevacizumab, for the treatment of certain of EYLEA's indications, and we are aware of another company developing an ophthalmic formulation of such product. In DME and RVO, EYLEA also competes with intravitreal implants of corticosteroids. We are also aware of a number of companies working on the development of product candidates and extended delivery devices for the potential treatment of one or more of EYLEA's indications, including those that act by blocking VEGF and VEGF receptors (including therapies designed to extend the treatment interval) and/or other targets (such as Ang2), as well as siRNAs that modulate gene expression. In addition, we are aware of several companies developing biosimilar versions of EYLEA and other approved anti-VEGF treatments. Other potentially competitive products in development include products for use in combination with EYLEA and/or other anti-VEGF treatments, small-molecule tyrosine kinase inhibitors, gene therapies, and other eye-drop formulations, devices, and oral therapies. There also is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, even though ZALTRAP has not been manufactured and formulated for use in intravitreal injections. 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.

The market for Dupixent's current and potential future indications is also competitive. In atopic dermatitis, there are several topical ointments or agents either approved or in development. In addition, a number of companies are developing antibodies against IL-13, IL-13Ra1, OX40, IL-31R, and/or IL-1alpha. Several companies are also studying JAK inhibitors for atopic dermatitis. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor or immunoglobulin E; and some of these antibodies, if approved in this indication, may also compete with Dupixent in CRSwNP. Dupixent also faces competition from orally administered small molecule agents and inhaled products in asthma and potential future indications. 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, including antibodies against thymic stromal lymphopoietin (TSLP), the IL-33 ligand, or the IL-33 receptor (ST2).

Libtayo also faces significant competition. There are several competitors that are marketing and/or developing antibodies against PD-1 and/or PDL-1, including Merck's Keytruda, Bristol-Myers Squibb's Opdivo, and Roche's Tecentriq.

There is also significant actual and potential future competition for other products marketed by us and/or our collaborators under our collaboration agreements with them. For example, there are several companies that are marketing and/or developing antibodies against PCSK9 and IL-6 and/or IL-6R, which currently (or, for antibodies in development, may in the future if approved) compete with Praluent and Kevzara, respectively.

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 other 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. We are also aware of other 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. 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 product 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 some of our marketed products.

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 (and, in Japan, Santen pursuant to

a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate, as in effect from time to time) for sales, marketing, and distribution of EYLEA in countries outside the United States.

In addition, under the terms of our Antibody Collaboration (which, as previously announced, is expected to be revised to give effect to a new arrangement for Praluent and Kevzara, as described further in Part I, Item 1. "Business - Collaboration Agreements - *Collaborations with Sanofi*" (the "Antibody Collaboration Restructuring")) and our IO Collaboration, we and Sanofi co-commercialize Dupixent and Libtayo in the United States. As a result, we rely in part on Sanofi's sales and marketing organization in the United States for these products. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of any of such products may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent in the United States. For example, Sanofi records product sales for Dupixent in the United States, serves as the Dupixent lead regulatory party (*e.g.*, is responsible for regulatory filings and negotiations relating to it) in the United States, and leads negotiations with payors relating to this product. We also rely on Sanofi for sales, marketing, and distribution of Dupixent and Libtayo in countries outside the United States. In addition, after the Antibody Collaboration Restructuring has been finalized, Sanofi is expected to obtain sole global rights to Kevzara and sole rights to Praluent outside the United States and will be solely responsible for commercialization of these products (as well as development and commercialization expenses) in the relevant jurisdictions; our rights will be limited to receiving a royalty on corresponding net product sales realized by Sanofi.

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 certain of our products and product candidates in the time expected, or at all, would be materially harmed*" below.

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 payors 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, payors, 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, Libtayo, and ARCALYST 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, 2019, our gross product sales of such products to two customers accounted on a combined basis for 90% 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 these products will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of these products to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, 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. We will need to establish commercial capabilities outside the United States as a result of any exercise of our option to co-commercialize a product outside the United States. For example, we have recently exercised our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States. In addition, there may be other circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to 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 or co-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 or the co-commercialization of a product 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 or our collaborators 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 or our collaborators 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 may be materially harmed.

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

In the United States, we (which, for purposes of this risk factor, includes our collaborators, unless otherwise stated or required by the context) 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.

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 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 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. We and our collaborators must maintain regulatory compliance for the products we or they commercialize in foreign jurisdictions. From time to time, we may hold a product's marketing approval in a jurisdiction outside the United States where we may have less experience and where our regulatory capabilities may be more limited. 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, and may ask for additional data in order to begin a clinical study. 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 market that product or any other product in those countries.

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

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (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 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 osteoarthritis trials were 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.

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 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 and Libtayo are 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 Dupixent or Libtayo (as applicable) 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, cold sores, oropharyngeal pain, and eosinophilia; and 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. These and other complications or side effects could harm further development and/or commercialization of Dupixent and Libtayo (as applicable).

There also are risks inherent in subcutaneous injections (which are used for administering most of our antibody-based products and product candidates), 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 utilizing this method of administration.

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

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

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

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody-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, commercialization, and other risks.

Many of our products are used and some of our products and product candidates may be used, if approved, in combination with a drug-delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. For example, the FDA recently approved the 2mg EYLEA pre-filled syringe, which has launched commercially. The success of our products and 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 are not well established, 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 and manufacture the devices; to conduct the studies and prepare related documentation 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 or 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 and manufacture 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.

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 could 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 (the "EPO") (currently pending before its Boards of Appeal), as described in Note 16 to our Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (the "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/or Sanofi relating to Praluent and patent infringement proceedings relating to Dupixent, as described in Note 16 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 16 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), Libtayo (cemiplimab), Praluent (alirocumab), and Kevzara (sarilumab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF; evinacumab, an antibody to ANGPTL3; REGN-EB3, a multi-antibody therapy for Ebola; garetosmab, an antibody to Activin A; pozelimab, an antibody to C5; and REGN1979, a bispecific antibody targeting CD20 and CD3.

Although we do not believe that any of our products or our late-stage antibody-based product candidates infringe 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.

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. 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. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. We are aware of several companies developing biosimilar versions of EYLEA. The loss of market exclusivity for a product (such as EYLEA) would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

We rely on limited internal and contracted manufacturing and supply chain capacity, which could adversely affect our ability to commercialize our marketed products and, if approved, our product candidates and to advance our clinical pipeline.

We have large-scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. Manufacturing facilities operated by us and by third-party contract manufacturers engaged by us would be inadequate to produce the active pharmaceutical ingredients of our current marketed products and our 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 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, including with respect to drug-delivery devices (such as a pre-filled syringe, patch pump, auto-injector, or other delivery system). 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 with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, 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 and establishing fill/finish capabilities 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.

In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. 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, time, and various regulatory approvals and permits. This also holds true for establishing fill/finish capabilities in the future, for which we have taken initial steps. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill/finish activities. 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 and any future fill/finish activities 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 or any future fill/finish 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, 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 (including our ability to conduct any fill/finish activities 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 apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of our marketed products 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 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 collaborators' 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 testing of our products and product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain regulatory restrictions on using these biological source materials. If we or our collaborators are required to substitute for these sources to comply with such regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

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. 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 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 payor. 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 described further in Note 16 to our Consolidated Financial Statements included in this report, we are cooperating with pending government investigations concerning certain of our business activities. Any adverse finding, allegation, or exercise of enforcement or regulatory discretion in such investigations could harm our business, prospects, operating results, and financial condition.

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 continue to dedicate significant resources to comply with these requirements and need 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 ability to expand internationally, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

As a fully integrated biotechnology 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, intellectual property rights, and the framework for dispute resolution and asserting our rights against others, 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 payors, 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.

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, effective January 31, 2020, the United Kingdom commenced an exit from the EU, commonly referred to as "Brexit." During a transition period (set to expire on December 31, 2020), the British government will continue to negotiate the terms of the United Kingdom's future relationship with the EU. The outcome of these negotiations is uncertain, and we do not know to what extent Brexit will ultimately 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). Recommendations by the Organization for Economic Co-operation and Development and the European Union Anti-Tax Avoidance Directive require companies to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny. Even though we regularly assess the information provided to tax authorities in determining the appropriateness of our tax reserves, such tax authorities could take a position that is contrary to our expectations, and the result could adversely affect our provision for income tax and our current rate.

We face potential liability related to the personal information we collect from individuals, data brokers, or research institutions or obtain from clinical trials sponsored by us or our collaborators.

Most U.S. 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, we could be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. There are instances where we collect and maintain sensitive personally identifiable information, which may include health information outside of the scope of HIPAA. This information may be received throughout the clinical trial process, in the course of our research collaborations, and directly from individuals who enroll in our patient assistance programs. In the case of a breach of personal information we may be subject to state breach notification laws requiring notification of affected individuals and state regulators.

Our patient assistance programs and product marketing activities as part of which we collect California resident personal data are subject to the CCPA. The CCPA is a consumer protection law that provides California residents with personal data privacy rights and became effective on January 1, 2020. The CCPA requires us, among other things, to update our notices and develop new processes internally and with our partners. There are fines, penalties, and a private right of action resulting from non-compliance with the CCPA. Several other U.S. states have introduced similar consumer protection laws that may go into effect in the near future.

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) implicate international data protection laws, including the European Union's GDPR. 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 have issued or 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, 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 and other personal information. Moreover, individuals about whom we or our collaborators obtain health or other personal information, as well as the providers and third parties 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, local, or foreign 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 the products that we are co-developing with Sanofi under our Antibody Collaboration (*i.e.*, after giving effect to the Antibody Collaboration Restructuring, Dupixent and REGN3500), 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.

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 have all rights to, and we fund and conduct on our own all research, development, manufacturing, and commercialization activities to support, all of our immuno-oncology product candidates other than MUC16xCD3 Program antibodies (such as REGN4018) and BCMAxCD3 Program antibodies (such as REGN5458 and REGN5459). If Sanofi does not elect to co-develop MUC16xCD3 Program antibodies or BCMAxCD3 Program antibodies 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 BCMAxCD3 Program antibodies and/or MUC16xCD3 Program antibodies under our IO Collaboration, Sanofi will initially fund the development expenses incurred in connection with the development of BCMAxCD3 Program antibodies, for which Sanofi will be the principal controlling party, and half of the development expenses incurred in connection with the clinical development of MUC16xCD3 Program antibodies, 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, if Sanofi elects to co-develop BCMAxCD3 Program antibodies, Sanofi will lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. We also rely on Sanofi to lead commercialization efforts outside the United States for Libtayo. Following regulatory approval, we will rely on Sanofi to lead (i) the commercialization efforts in the United States for BCMAxCD3 Program antibodies and (ii) the commercialization efforts outside the United States for MUC16xCD3 Program antibodies and BCMAxCD3 Program antibodies.

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 or our IO Collaboration (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, 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 the products subject to such collaborations, 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, as in effect from time to time, 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 issues for 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 Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, 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 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 net product sales of EYLEA and funding we receive under our collaboration agreements (including our share of profits in connection with commercialization of EYLEA and Dupixent under our collaboration agreements with Bayer and Sanofi, respectively), or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

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

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by our current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements (including our share of profits in connection with commercialization of EYLEA and Dupixent under our collaboration agreements with Bayer and Sanofi, respectively), 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. 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 Tarrytown, New York, 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, Canadian dollar, 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. Conversely, 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, 2019, we had $1.618 billion in cash and cash equivalents and $4.853 billion in marketable securities (including $618.8 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.

The elimination of LIBOR could adversely affect our business, operating results, and financial condition.

In July 2017, the United Kingdom regulator that regulates the London Interbank Offered Rate ("LIBOR") announced its intention to phase out LIBOR rates by the end of 2021. No consensus exists as to what rate or rates may become accepted alternatives to LIBOR or whether LIBOR rates will cease to be published or supported before or after 2021. A transition away from LIBOR as a benchmark for establishing the applicable interest rate may adversely affect our outstanding variable-rate indebtedness and interest rate swaps, as well as floating-rate debt securities we hold. For example, if a published U.S. dollar LIBOR rate is unavailable

after 2021, the rent payments for the leased facilities in Tarrytown, New York, which are indexed to LIBOR, will be determined using various alternative methods, any of which may result in interest obligations which are more than, or do not otherwise correlate over time with, the payments that would have been made on such debt if U.S. dollar LIBOR was available in its current form.

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 (or the expectation of any such sales);
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all;
- 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. As a result, the public float of our Common Stock (*i.e.*, the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common

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

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2019, our five largest shareholders (including our largest shareholder Sanofi) plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 45.2% 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, 2019. As of December 31, 2019, Sanofi beneficially owned 23,350,365 shares of our Common Stock, representing approximately 21.5% of the shares of Common Stock then outstanding. Under our January 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time 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 869,828 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 an amendment to its Schedule 13D filed on December 9, 2019, Sanofi disclosed that, following expiration of the "lock-up," it may in its discretion dispose of or collateralize all or a portion of the Common Stock beneficially owned by it at any time or from time to time in accordance with the terms of the amended and restated investor agreement. 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.

There can be no assurance that we will continue to repurchase shares of our Common Stock or that we will repurchase shares at favorable prices.

Our board of directors previously authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock (of which $746.0 million remained available as of December 31, 2019). Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will continue to repurchase shares of our Common Stock at favorable prices, if at all.

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, 2019, holders of Class A Stock held 14.6% 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, 2019:

- our current executive officers and directors beneficially owned 9.8% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2019, and 20.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2019; and
- our five largest shareholders (including our largest shareholder Sanofi) plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 45.2% 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, 2019. In addition, these five shareholders plus our Chief Executive Officer held approximately 51.4% of the combined voting power of our outstanding shares of Common Stock and Class

A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2019.

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.

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) (the "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 373,880 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 495,948 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.*"

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. A similar "standstill" prohibition applies to Bayer pursuant to our 2014 PDGFR-beta license and collaboration agreement with Bayer (which agreement was terminated on July 31, 2017 by agreement of the parties but whose "standstill" provisions continue to be in effect until July 31, 2022 unless they expire earlier upon the occurrence of certain specified events).

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, equity 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.

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 1,244,000 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.

Rensselaer, New York

We own facilities in Rensselaer, New York totaling approximately 900,000 square feet of research, manufacturing, office, and warehouse space. This includes approximately 212,000 square feet of warehouse space which we constructed on a 130-acre parcel of land near our Rensselaer facility. We are in the process of further developing this property, primarily in connection with constructing a fill/finish facility.

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 16 to our Consolidated Financial Statements included in this report.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market for Registrant's Common Equity

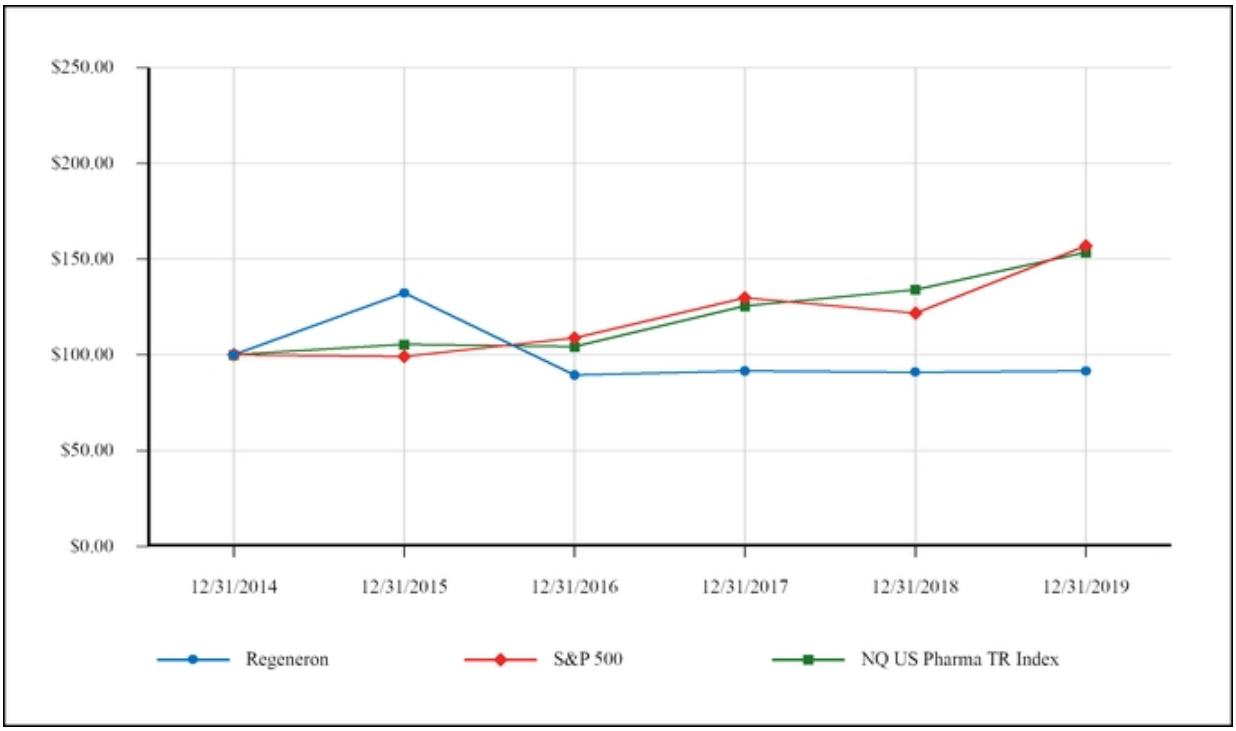
Our Common Stock, par value $.001 per share, is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

As of January 31, 2020, there were 166 shareholders of record of our Common Stock and 16 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, 2014 through December 31, 2019. The comparison assumes that $100 was invested on December 31, 2014 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.



	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Regeneron	$ 100.00	$ 132.33	$ 89.48	$ 91.64	$ 91.04	$ 91.52
S&P 500	$ 100.00	$ 99.27	$ 108.74	$ 129.86	$ 121.76	$ 156.92
NQ US Pharma TR Index	$ 100.00	$ 105.43	$ 104.29	$ 125.57	$ 134.11	$ 153.57

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

Issuer Purchases of Equity Securities

The table below reflects shares of Common Stock we repurchased under our share repurchase program, as well as Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock awards or restricted stock units granted under one of our long-term incentive plans, during the fourth quarter of 2019. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - *Share Repurchase Program*" for further details of the share repurchase program.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
11/1/2019–11/30/2019	509,365	$ 343.35	508,314	$ 825,664,565
12/1/2019–12/31/2019	214,282	$ 371.59	214,282	$ 745,967,321
Total	723,647 [(a)]		722,596 [(a)]	

[(a)] The difference between the total number of shares purchased and the total number of shares purchased as part of a publicly announced program is related to Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock awards or restricted stock units granted under one of our long-term incentive plans.

Item 6. Selected Financial Data

The selected financial data set forth below for the years ended December 31, 2019, 2018, and 2017 and as of December 31, 2019 and 2018 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, 2016 and 2015 and as of December 31, 2017, 2016, and 2015 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)	**2019**	**2018**	**2017**	**2016**	**2015**
Statement of Operations Data:					
Revenues:					
Net product sales	$ 4,834.4	$ 4,106.2	$ 3,718.5	$ 3,338.4	$ 2,689.5
Sanofi and Bayer collaboration revenue	2,615.6	2,187.8	1,815.3	1,403.0	1,339.4
Other revenue	413.4	416.8	338.4	119.0	74.8
	7,863.4	6,710.8	5,872.2	4,860.4	4,103.7
Expenses:					
Research and development[1]	3,036.6	2,186.1	2,075.1	2,052.3	1,620.6
Selling, general, and administrative	1,834.8	1,556.2	1,320.4	1,177.7	838.5
Cost of goods sold	362.3	180.0	202.5	194.6	241.7
Cost of collaboration and contract manufacturing	419.9	254.1	194.6	105.1	151.0
	5,653.6	4,176.4	3,792.6	3,529.7	2,851.8
Income from operations	2,209.8	2,534.4	2,079.6	1,330.7	1,251.9
Other income (expense), net	219.3	19.1	(1.1)	(0.9)	(26.8)
Income before income taxes	2,429.1	2,553.5	2,078.5	1,329.8	1,225.1
Income tax expense[2]	(313.3)	(109.1)	(880.0)	(434.3)	(589.0)
Net income	$ 2,115.8	$ 2,444.4	$ 1,198.5	$ 895.5	$ 636.1
Net income per share - basic	$ 19.38	$ 22.65	$ 11.27	$ 8.55	$ 6.17
Net income per share - diluted	$ 18.46	$ 21.29	$ 10.34	$ 7.70	$ 5.52

	As of December 31,				
(In millions)	**2019**	**2018**	**2017**	**2016**	**2015**
Balance Sheet Data:					
Cash, cash equivalents, and marketable securities (current and non-current)	$ 6,471.1	$ 4,564.9	$ 2,896.0	$ 1,902.9	$ 1,677.4
Total assets	$ 14,805.2	$ 11,734.5	$ 8,764.3	$ 6,973.5	$ 5,609.1
Finance lease liabilities	$ 713.9	$ 708.5	$ 703.5	$ 481.1	$ 364.7
Stockholders' equity	$ 11,089.7	$ 8,757.3	$ 6,144.1	$ 4,449.2	$ 3,654.8

[1] Research and development expenses for the year ended December 31, 2019 includes a $400.0 million up-front payment to Alnylam in connection with our collaboration agreement. See Part I, Item 1. "Collaboration Agreements - *Collaboration with Alnylam*") for further details.

[2] Income taxes for the year ended December 31, 2018 includes a $162.1 million income tax benefit related to 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 15 to our Consolidated Financial Statements for further details.

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. Refer to Part II, Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (filed with the SEC on February 7, 2019) for additional discussion of our financial condition and results of operations for the year ended December 31, 2017, as well as our financial condition and results of operations for the year ended December 31, 2018 compared to the year ended December 31, 2017.

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, pain, infectious diseases, and rare diseases.

As described in Part I, Item 1. "Business," we currently have seven products that have received marketing approval and 22 product candidates in clinical development, all of which were discovered in our research laboratories. Refer to Part I, Item 1. "Business" for a summary of our clinical programs.

Our ability to generate profits and to generate positive cash flow from operations over the next several years depends significantly on the continued success in commercializing EYLEA and Dupixent. 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, 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.

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. net product 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 customer.

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 payor 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. 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 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, a 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 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.

Stock-based Compensation

We recognize stock-based compensation expense for grants 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.

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. Deferred tax assets and liabilities are determined as 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 all available evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, results of recent operations, and our historical earnings experience by taxing jurisdiction. 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 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.

Results of Operations

Net Income

	Year Ended December 31,		
(In millions, except per share data)	**2019**	**2018**	**2017**
Revenues	$ 7,863.4	$ 6,710.8	$ 5,872.2
Operating expenses	(5,653.6)	(4,176.4)	(3,792.6)
Income from operations	2,209.8	2,534.4	2,079.6
Other income (expense), net	219.3	19.1	(1.1)
Income before income taxes	2,429.1	2,553.5	2,078.5
Income tax expense	(313.3)	(109.1)	(880.0)
Net income	$ 2,115.8	$ 2,444.4	$ 1,198.5
Net income per share - diluted	$ 18.46	$ 21.29	$ 10.34

Revenues

	Year Ended December 31,			$ Change	
(In millions)	**2019**	**2018**	**2017**	**2019 vs. 2018**	**2018 vs. 2017**
Net product sales in the United States:					
EYLEA	$ 4,644.2	$ 4,076.7	$ 3,701.9	$ 567.5	$ 374.8
Libtayo	175.7	14.8	—	160.9	14.8
ARCALYST	14.5	14.7	16.6	(0.2)	(1.9)
Sanofi and Bayer collaboration revenue:					
Sanofi	1,426.8	1,111.1	877.2	315.7	233.9
Bayer	1,188.8	1,076.7	938.1	112.1	138.6
Other revenue	413.4	416.8	338.4	(3.4)	78.4
Total revenues	$ 7,863.4	$ 6,710.8	$ 5,872.2	$ 1,152.6	$ 838.6

Net Product Sales

Net product sales of EYLEA in the United States increased in 2019 compared to 2018 due to higher sales volume, partly offset by an increase in sales-related deductions primarily due to higher rebates and discounts. On September 28, 2018, the FDA approved Libtayo for the treatment of patients with metastatic or locally advanced CSCC and sales commenced thereafter.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts; distribution-related fees; and other sales-related deductions. 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, 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
Provisions	423.2	242.9	61.8	727.9
Credits/payments	(384.0)	(238.5)	(40.7)	(663.2)
Balance as of December 31, 2019	$ 80.3	$ 46.4	$ 29.4	$ 156.1

Sanofi Collaboration Revenue

	Year Ended December 31,		
(In millions)	**2019**	**2018**	**2017**
Antibody:			
Reimbursement of research and development expenses - Discovery Agreement	—	—	$ 130.0
Reimbursement of research and development expenses - License and Collaboration Agreement	$ 277.7	$ 265.3	378.4
Reimbursement of commercialization-related expenses[1]	479.9	417.2	368.8
Reimbursement for manufacturing of commercial supplies[2]	206.7	127.6	35.1
Regeneron's share of profits (losses) in connection with commercialization of antibodies	209.3	(227.0)	(442.6)
Other	(1.5)	(24.1)	84.0
Total Antibody	1,172.1	559.0	553.7
Immuno-oncology:			
Reimbursement of research and development expenses - Discovery Agreement	54.1	154.4	138.8
Reimbursement of research and development expenses - License and Collaboration Agreement	108.9	157.4	101.2
Reimbursement of commercialization-related expenses[1]	10.3	8.9	7.0
Amounts recognized in connection with up-front payments received	92.7	243.8	80.0
Other	(11.3)	(12.4)	(3.5)
Total Immuno-oncology	254.7	552.1	323.5
Total Sanofi collaboration revenue	$ 1,426.8	$ 1,111.1	$ 877.2

[1] The corresponding commercialization-related costs incurred by us are recorded within Selling, general and administrative expense.

[2] The corresponding costs incurred by us in connection with such production is recorded within Cost of collaboration and contract manufacturing.

Antibody

The Company's Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") with Sanofi ended on December 31, 2017 without any extension and, therefore, there was no further funding from Sanofi under the Antibody Discovery Agreement after 2017.

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

Regeneron's share of profits (losses) in connection with the commercialization of Dupixent, Praluent, and Kevzara is summarized below:

	Year Ended December 31,		
(In millions)	**2019**	**2018**	**2017**
Dupixent, Praluent, and Kevzara net product sales*	$ 2,811.0	$ 1,325.4	$ 464.5
Regeneron's share of collaboration profits (losses)	233.0	(227.0)	(442.6)
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(23.7)	—	—
Regeneron's share of profits (losses) in connection with commercialization of antibodies	$ 209.3	$ (227.0)	$ (442.6)
Regeneron's share of collaboration profits as a percentage of Dupixent, Praluent, and Kevzara net product sales	7%	**	**

* Global net product sales of Dupixent, Praluent, and Kevzara are recorded by Sanofi

** Percentage not meaningful

We and Sanofi share commercial expenses related to Dupixent, Praluent, and Kevzara 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 profits/losses in connection with the companies' commercialization of Dupixent, Praluent, and Kevzara within Sanofi collaboration revenue. During 2019, Sanofi collaboration revenues in connection with commercialization of antibodies increased, compared to 2018, primarily due to our share of higher Dupixent profits. See Part I, 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.

In December 2019, we and Sanofi announced our intent to restructure the antibody collaboration for Kevzara and Praluent; completion of the proposed arrangement is expected to be finalized in the first quarter of 2020. Refer to Part I, Item 1. "Business - Collaboration Agreements - *Collaborations with Sanofi - Antibody*" for further details.

Immuno-Oncology

Sanofi's reimbursement of immuno-oncology research and development costs under our IO Discovery Agreement decreased in 2019, compared to 2018 and 2017, due to the impact of the Amended IO Discovery Agreement (see Part I, Item 1. "Business - Collaboration Agreements - *Collaborations with Sanofi - Immuno-Oncology* for further details). In 2018, we also recorded cumulative catch-up adjustments to revenue of $135.0 million (included in "Amounts recognized in connection with up-front payments received" in the Sanofi collaboration revenue table above) arising from changes in the estimate of the stage of completion of the collaborations' immuno-oncology programs, primarily in connection with the Amended IO Discovery Agreement.

Bayer Collaboration Revenue

	Year Ended December 31,		
(In millions)	**2019**	**2018**	**2017**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 1,091.4	$ 992.3	$ 802.3
Reimbursement of development expenses	23.0	10.8	31.1
Other	74.4	73.6	104.7
Total Bayer collaboration revenue	$ 1,188.8	$ 1,076.7	$ 938.1

Bayer records net product sales of EYLEA outside the United States. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below:

(In millions)	Year Ended December 31, 2019	2018	2017
EYLEA net product sales outside the United States	$ 2,897.4	$ 2,668.9	$ 2,226.9
Regeneron's share of collaboration profit from sales outside the United States	$ 1,148.0	$ 1,045.9	$ 856.1
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(56.6)	(53.6)	(53.8)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 1,091.4	$ 992.3	$ 802.3
Regeneron's net profit as a percentage of EYLEA net product sales outside the United States	38%	37%	36%

Other Revenue

(In millions)	Year Ended December 31, 2019	2018	2017
Teva collaboration revenue:			
Reimbursement of research and development expenses	$ 122.9	$ 129.5	$ 115.1
Other	83.6	115.1	106.4
Total Teva collaboration revenue	206.5	244.6	221.5
Other revenue	206.9	172.2	116.9
Total other revenue	$ 413.4	$ 416.8	$ 338.4

In addition to Teva collaboration revenue (which is earned in connection with the development of fasinumab), "Other revenue" in the table above includes, but is not limited to:

- recognition of a portion of deferred revenue from up-front and other payments received 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;
- 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 agreements with BARDA related to REGN-EB3 for the treatment of Ebola;
- recognition of revenue in connection with sequencing of samples by the RGC for its customers.

Other revenue of $416.8 million in 2018 also included the impact of adopting ASC 606, *Revenue from Contracts with Customers*, as the new standard resulted in certain changes to the timing of revenue recognition related to our collaboration agreements. Amounts in periods prior to 2018 have not been adjusted in connection with the adoption of this standard.

Expenses

(In millions, except headcount data)	Year Ended December 31, 2019	2018	2017	$ Change 2019 vs. 2018	2018 vs. 2017
Research and development	$ 3,036.6	$ 2,186.1	$ 2,075.1	$ 850.5	$ 111.0
Selling, general, and administrative	1,834.8	1,556.2	1,320.4	278.6	235.8
Cost of goods sold[1]	362.3	180.0	202.5	182.3	(22.5)
Cost of collaboration and contract manufacturing[2]	419.9	254.1	194.6	165.8	59.5
Total operating expenses	$ 5,653.6	$ 4,176.4	$ 3,792.6	$ 1,477.2	$ 383.8
Average headcount	7,773	6,906	5,780	867	1,126

[1] Cost of goods sold includes costs in connection with producing commercial supplies for products that are sold by Regeneron in the United States (*i.e.*, EYLEA, Libtayo, and ARCALYST) and any royalties we are obligated to pay on such sales, period costs for our Limerick manufacturing facility, and amounts we are obligated to pay to Sanofi for its share of Libtayo U.S. gross profits.

[2] Cost of collaboration and contract manufacturing primarily includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer.

Operating expenses in 2019, 2018, and 2017 included a total of $464.3 million, $427.4 million, and $507.3 million, respectively, of non-cash compensation expense related to awards granted under our long-term incentive plans. Non-cash compensation expense in 2019 and 2018 benefited from a revision in our estimate of the number of stock options that were expected to be forfeited. As of December 31, 2019, unrecognized non-cash compensation expense related to outstanding stock options and unvested restricted stock was $521.9 million and $274.6 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 3.4 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, 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, and other costs related to activities that benefit multiple projects. Clinical manufacturing costs primarily consist of costs to manufacture bulk drug product for clinical development purposes as well as related external drug filling, packaging, and labeling costs. Clinical manufacturing costs also includes pre-launch commercial supplies which did not meet the criteria to be capitalized as inventory (see "Critical Accounting Policies and Use of Estimates - Inventories" above).

(In millions)	Year Ended December 31, 2019	2018*	2017*	$ Change 2019 vs. 2018	2018 vs. 2017
Direct research and development expenses:					
Fasinumab	$ 203.4	$ 174.3	$ 123.0	$ 29.1	$ 51.3
Libtayo (cemiplimab)	160.8	129.4	84.7	31.4	44.7
Dupixent (dupilumab)	104.3	102.9	142.3	1.4	(39.4)
EYLEA	55.4	28.8	30.7	26.6	(1.9)
Praluent (alirocumab)	42.6	59.9	80.1	(17.3)	(20.2)
Evinacumab	36.1	21.9	14.3	14.2	7.6
Up-front payments related to license and collaboration agreements	430.0	—	25.0	430.0	(25.0)
Other product candidates in clinical development and other research programs	277.0	166.2	206.3	110.8	(40.1)
Total direct research and development expenses	1,309.6	683.4	706.4	626.2	(23.0)
Indirect research and development expenses:					
Payroll and benefits	705.8	607.0	579.0	98.8	28.0
Lab supplies and other research and development costs	119.9	95.4	63.4	24.5	32.0
Occupancy and other operating costs	304.7	246.3	203.0	58.4	43.3
Total indirect research and development expenses	1,130.4	948.7	845.4	181.7	103.3
Clinical manufacturing costs	596.6	554.0	523.3	42.6	30.7
Total research and development expenses	$ 3,036.6	$ 2,186.1	$ 2,075.1	$ 850.5	$ 111.0

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

Research and development expenses in 2019 included a $400.0 million up-front payment to Alnylam (see Part I, Item 1. "Collaboration Agreements - *Collaboration with Alnylam*" for further information). Research and development expenses included non-cash compensation expense of $250.4 million, $229.0 million, and $271.9 million in 2019, 2018, and 2017, 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 and other applicable 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 2019, compared to 2018, primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Dupixent and EYLEA, additional accruals for loss contingencies associated with ongoing litigation, and higher contributions to independent not-for-profit patient assistance organizations. In addition, in the fourth quarter of 2019, we recorded a $35.2 million charge related to employee separation costs, as the Company has eliminated certain commercialization activities and related headcount in connection with the proposed restructuring of the antibody agreement with Sanofi (as described in Part I, Item 1. "Business - Collaboration Agreements - *Collaborations with Sanofi - Antibody*"). Selling, general, and administrative expenses also included $167.7 million, $169.2 million, and $208.4 million of non-cash compensation expense in 2019, 2018, and 2017, respectively.

Cost of Goods Sold

Cost of goods sold increased in 2019, compared to 2018, primarily due to Libtayo sales in the United States, including (i) our obligation to pay Sanofi its share of Libtayo U.S.gross profits and (ii) third-party royalties. In addition, Cost of goods sold for the years ended December 31, 2019 and 2018 included inventory write-downs and reserves totaling $73.8 million and $12.5 million, respectively.

Cost of Collaboration and Contract Manufacturing

The increase in Cost of collaboration and contract manufacturing in 2019, compared to 2018, was primarily due to the recognition of manufacturing costs associated with higher sales of Dupixent.

Other Income (Expense)

Other income (expense), net, was positively impacted in 2019 by the recognition of unrealized gains on equity securities. Other income (expense), net, in 2019, compared to 2018, was also positively impacted by increased interest income earned on available-for-sale debt securities primarily due to higher average investment balances.

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)	**2019**	**2018**	**2017**
Income tax expense	$ 313.3	$ 109.1	$ 880.0
Effective tax rate	12.9%	4.3%	42.3%

Our effective tax rate for 2019 was positively impacted, compared to the U.S. federal statutory rate, primarily by federal tax credits for research activities, stock-based compensation, and the foreign-derived intangible income deduction. 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 bill known as the "Tax Cuts and Jobs Act" (the "Act") (as further described below).

In December 2017, the Act was signed into law. The Act, which became effective with respect to most of its provisions as of January 1, 2018, included 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), 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. 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.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

	As of December 31,		
(In millions)	**2019**	**2018**	**$ Change**
Financial assets:			
Cash and cash equivalents	$ 1,617.8	$ 1,467.7	$ 150.1
Marketable securities - current	1,596.5	1,342.2	254.3
Marketable securities - noncurrent	3,256.8	1,755.0	1,501.8
	$ 6,471.1	$ 4,564.9	$ 1,906.2
Working capital:			
Current assets	$ 7,689.1	$ 6,447.6	$ 1,241.5
Current liabilities	2,096.6	1,442.8	653.8
	$ 5,592.5	$ 5,004.8	$ 587.7

As of December 31, 2019, we also had borrowing availability of $750.0 million under a revolving credit facility (see further description under "*Credit Facility*" below).

Sources and Uses of Cash for the Years Ended December 31, 2019, 2018, and 2017

	Year Ended December 31,			$ Change	
(In millions)	**2019**	**2018**	**2017**	**2019 vs. 2018**	**2018 vs. 2017**
Cash flows provided by operating activities	$ 2,430.0	$ 2,195.1	$ 1,307.1	$ 234.9	$ 888.0
Cash flows used in investing activities	$ (2,027.8)	$ (1,463.0)	$ (1,005.2)	$ (564.8)	$ (457.8)
Cash flows used in financing activities	$ (252.1)	$ (77.1)	$ (24.4)	$ (175.0)	$ (52.7)

Cash Flows from Operating Activities

2019

Our net income of $2.116 billion in 2019 was negatively impacted by an up-front payment of $400.0 million made to Alnylam pursuant to our collaboration agreement. Our net income in 2019 was impacted by several non-cash items, including unrealized gains (net) on equity securities and inventory write-downs and reserves (see "Results of Operations" above), as well as the impact of Sanofi satisfying its Libtayo development funding obligation in shares of Regeneron stock (see "Sanofi Funding of Certain Development Costs" below). Deferred taxes as of December 31, 2019 increased by $130.6 million, compared to December 31, 2018, primarily due to the tax treatment of the up-front payment made to Alnylam and non-cash compensation expense. Deferred revenue as of December 31, 2019 increased compared to December 31, 2018 partially due to the impact of the receipt of a $461.9 million payment from Sanofi in connection with the termination of the 2015 IO Discovery Agreement (as described in Part I, Item 1. "Collaboration Agreements - *Collaborations with Sanofi - Immuno-Oncology*").

2018

Our net income of $2.444 billion in 2018 included the recognition of cumulative catch-up adjustments of $135.0 million within revenue primarily in connection with the termination of the 2015 IO Discovery Agreement and other non-cash items, including $75.8 million in connection with Sanofi satisfying its Libtayo development funding obligation in shares of Regeneron stock 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.

Cash Flows from Investing Activities

In 2019, we purchased $400.0 million of Alnylam common stock in connection with entering into the collaboration agreement. Capital expenditures in 2019 included costs associated with the expanding our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, including the initiation of the construction of a fill/finish facility.

We expect to incur capital expenditures of $520 million to $620 million in 2020 primarily in connection with the continued expansion of our manufacturing facilities, including the fill/finish facility and equipment, and laboratory expansion and renovations at our Tarrytown, New York facilities.

Cash Flows from Financing Activities

During 2019, we paid an aggregate of $275.9 million to purchase shares of our Common Stock. See further descriptions under "*Share Repurchase Program*" and "*Sanofi Funding of Certain Development Costs*" below.

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, 2019.

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, 2019.

Share Repurchase Program

In November 2019, our board of directors authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. The share repurchase program permits the Company to effect repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. Repurchases may be made from time to time at management’s discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The program has no time limit and can be discontinued at any time. There can be no assurance as to the timing or number of shares of any repurchases in the future. We plan to finance the share repurchase program with available cash.

During 2019, we repurchased 722,596 shares of our Common Stock under the program and recorded the cost of the shares received, or $254.0 million, as Treasury Stock.

Sanofi Funding of Certain Development Costs

As described in Part I, Item 1. "Business - Collaborations - *Collaborations with Sanofi*," effective January 7, 2018, 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 869,828 shares remain available to be sold as of December 31, 2019) of our Common Stock directly or indirectly owned by Sanofi. During 2019, Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi), 210,733 shares of the Company's Common Stock to satisfy Sanofi's funding obligation related to Libtayo development costs. Consequently, we recorded $73.3 million related to the shares received as Treasury Stock during 2019. In addition, during 2019, Sanofi elected to sell, and we elected to purchase (in cash), 93,286 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 $29.4 million, as Treasury Stock during 2019.

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 "Lease 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 Lease 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 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 Lease 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 Lease 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, 2019.

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 the Credit Facility, funds generated by anticipated EYLEA and Dupixent 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 anticipated operating needs for the foreseeable future.

The following table summarizes our contractual obligations as of December 31, 2019.

		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]	$ 2,384.8	$ 1,485.2	$ 636.7	$ 228.6	$ 34.3
Operating and finance lease obligations[2]	75.6	29.8	37.2	4.3	4.3
Total contractual obligations	$ 2,460.4	$ 1,515.0	$ 673.9	$ 232.9	$ 38.6

[1] Primarily includes 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] Includes rent payments with respect to finance lease obligations in connection with our property leases in Tarrytown, New York, as described under "*Tarrytown, New York Leases*" above and Note 11 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 $210.8 million at December 31, 2019, 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 15 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, 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 11 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 are 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, 2019, our contingent reimbursement obligation to Bayer for EYLEA was approximately $270 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration and IO Collaboration was approximately $2.990 billion and $75 million, respectively. Therefore, we expect that, for the foreseeable future, a portion of our share of profits from sales under our collaborations with Bayer and Sanofi will be used to reimburse our collaborators 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 $48.6 million and $27.7 million decrease in the fair value of our investment portfolio as of December 31, 2019 and 2018, 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 Part II, 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 related to our variable rate lease 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. 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.

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 2019, 2018, and 2017, 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, including 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 2019, 2018, and 2017, we did not recognize any charges for write-offs of accounts receivable related to our marketed products. As of December 31, 2019 and 2018, three customers accounted on a combined basis for 97% and 99%, respectively, of our net trade accounts receivables.

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. We recorded $118.3 million of net unrealized gains and $41.9 million of net unrealized losses on equity securities in Other income (expense), net for the years ended December 31, 2019 and 2018, respectively.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this Item are included on pages F-1 through F-44 of this report. The supplementary financial information required by this Item is included at page F-44 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's 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, 2019 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, 2019. The effectiveness of the Company's internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears under Part IV, Item 15.

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

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2019 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 2020 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 2020 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 2020 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 2020 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 2020 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

The consolidated financial statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.

3. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation, as amended. (Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. (the "Registrant"), for the quarter ended June 30, 2015, filed August 4, 2015.)
3.2	Amended and Restated By-Laws. (Incorporated by reference from the Form 8-K for the Registrant filed December 21, 2016.)
4.1	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
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.)
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 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.)
10.2.3 +	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.)
10.2.4 +	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.)
10.2.5 +	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.)
10.2.6 +	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.)
10.2.7 +	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 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.)
10.2.8 +	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.)
10.2.9 +	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.)
10.2.10 +	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.)
10.2.11 +	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 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.)

10.2.12 +	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 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
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 (revised 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.14 +	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 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.15 +	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 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.16 +	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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
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 2019).
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 2019).
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 2019).
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 2019).
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 2019).
10.2.22 +	Form of performance restricted stock unit award agreement and related notice of grant for use in connection with the grant of performance restricted stock units to Leonard S. Schleifer, M.D., Ph.D., George D. Yancopoulos, M.D., Ph.D., and P. Roy Vagelos, M.D. under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan.
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.)
10.10.2**	Second Amendment Agreement, dated December 19, 2019, by and between Bayer HealthCare LLC and the Registrant.
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.)
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. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019).

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	Amended and Restated Participation Agreement, dated as of May 2, 2019, 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 May 3, 2019.)
10.24	Amended and Restated Lease and Remedies Agreement, dated as of May 2, 2019, 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 May 3, 2019.)
10.25	Amended and Restated Guaranty, dated as of May 2, 2019, made by Regeneron Pharmaceuticals, Inc., Regeneron Healthcare Solutions, Inc., and Regeneron Genetics Center LLC, as guarantors. (Incorporated by reference from the Form 8-K for the Registrant, filed May 3, 2019.)
10.26	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, for the quarter ended March 31, 2018, filed May 3, 2018.)
10.27**	Master Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2019, filed August 6, 2019).
10.27.1**	Form of Co-Co Collaboration Agreement (Exhibit B to Master Agreement contained in Exhibit 10.27).
10.27.2**	Form of License Agreement (Exhibit C to Master Agreement contained in Exhibit 10.27).
10.28**	Investor Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2019, filed August 6, 2019.)
10.29	Stock Purchase Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2019, filed August 6, 2019.)
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 Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Consolidated Balance Sheets as of December 31, 2019 and 2018; (ii) the Registrant's Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2019, 2018, and 2017; (iii) the Registrant's Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019, 2018, and 2017; (iv) the Registrant's Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018, and 2017; and (v) the notes to the Registrant's Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

** Certain confidential portions of this exhibit were omitted in accordance with Item 601(b)(10) of Regulation S-K.

\+ Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

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, 2020

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Robert E. Landry, 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, 2020
/s/ ROBERT E. LANDRY Robert E. Landry	*Executive Vice President, Finance and Chief Financial Officer (Principal Financial Officer)*	February 7, 2020
/s/ CHRISTOPHER R. FENIMORE Christopher R. Fenimore	*Vice President, Controller (Principal Accounting Officer)*	February 7, 2020
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	*President, Chief Scientific Officer, and Director*	February 7, 2020
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	*Chairman of the Board*	February 7, 2020
/s/ BONNIE L. BASSLER Bonnie L. Bassler, Ph.D.	*Director*	February 7, 2020
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	*Director*	February 7, 2020
/s/ N. ANTHONY COLES N. Anthony Coles, M.D.	*Director*	February 7, 2020
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	*Director*	February 7, 2020
/s/ CHRISTINE A. POON Christine A. Poon	*Director*	February 7, 2020
/s/ ARTHUR F. RYAN Arthur F. Ryan	*Director*	February 7, 2020
/s/ GEORGE L. SING George L. Sing	*Director*	February 7, 2020
/s/ MARC TESSIER-LAVIGNE Marc Tessier-Lavigne, Ph.D.	*Director*	February 7, 2020
/s/ HUDA Y. ZOGHBI Huda Y. Zoghbi, M.D.	*Director*	February 7, 2020

REGENERON PHARMACEUTICALS, INC.
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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, 2019 and 2018, and the related consolidated statements of operations and comprehensive income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 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, 2019, 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 appearing 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 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Recognition of Collaboration Revenue related to Research and Development Performance Obligations

As described in Note 1 to the consolidated financial statements, revenues related to collaboration arrangements where the Company satisfies performance obligations during the development phase over time are typically recognized using an input method on the basis of research and development costs incurred relative to the total expected costs which determines the extent of progress in each period towards completion of the performance obligation. Collaboration revenue for non-refundable up-front payments, development milestones, and payments for development activities, for which management used an input method, was $497.6 million for the year ended December 31, 2019. Management has disclosed that there is 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, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization related to these estimates.

The principal considerations for our determination that performing procedures relating to recognition of collaboration revenue related to research and development performance obligations is a critical audit matter are there was significant judgment by management when developing the total expected research and development costs to complete the performance obligation. This in turn led to significant audit effort in performing procedures and evaluating evidence to assess the reasonableness of the estimates of the costs to complete.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the determination of total expected research and development costs to complete the performance obligation. These procedures also included, among others, evaluating and testing management’s process for determining the total expected research and development costs at completion for a sample of contracts, which included evaluating the reasonableness of actual costs incurred and estimated costs to complete. Evaluating the reasonableness of estimated costs to complete involved assessing management’s ability to reasonably estimate costs to complete the performance obligation by (i) obtaining supporting evidence for expected development activities; (ii) evaluating the identification of circumstances that may warrant a modification to estimated costs to complete; and (iii) agreeing estimates of total budgeted costs to contracts or other agreements with collaboration partners.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 7, 2020

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

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

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,617.8	$ 1,467.7
Marketable securities	1,596.5	1,342.2
Accounts receivable - trade, net	2,100.0	1,723.7
Accounts receivable from Sanofi	260.6	226.4
Accounts receivable from Bayer	311.6	293.1
Inventories	1,415.5	1,151.2
Prepaid expenses and other current assets	387.1	243.3
Total current assets	7,689.1	6,447.6
Marketable securities	3,256.8	1,755.0
Property, plant, and equipment, net	2,890.4	2,575.8
Deferred tax assets	824.2	828.7
Other noncurrent assets	144.7	127.4
Total assets	$ 14,805.2	$ 11,734.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 418.1	$ 218.2
Accrued expenses and other current liabilities	1,086.8	772.1
Deferred revenue from Sanofi	395.5	246.7
Deferred revenue - other	196.2	205.8
Total current liabilities	2,096.6	1,442.8
Finance lease liabilities	713.9	708.5
Deferred revenue from Sanofi	509.7	279.3
Deferred revenue - other	109.3	184.9
Other noncurrent liabilities	286.0	361.7
Total liabilities	3,715.5	2,977.2
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred Stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,848,970 in 2019 and 1,911,354 in 2018	—	—
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 113,288,103 in 2019 and 111,084,951 in 2018	0.1	0.1
Additional paid-in capital	4,428.6	3,911.6
Retained earnings	7,379.8	5,254.3
Accumulated other comprehensive income (loss)	21.1	(12.3)
Treasury Stock, at cost; 4,860,123 shares in 2019 and 3,990,021 shares in 2018	(739.9)	(396.4)
Total stockholders' equity	11,089.7	8,757.3
Total liabilities and stockholders' equity	$ 14,805.2	$ 11,734.5

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

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Statements of Operations			
Revenues:			
Net product sales	$ 4,834.4	$ 4,106.2	$ 3,718.5
Sanofi collaboration revenue	1,426.8	1,111.1	877.2
Bayer collaboration revenue	1,188.8	1,076.7	938.1
Other revenue	413.4	416.8	338.4
	7,863.4	6,710.8	5,872.2
Expenses:			
Research and development	3,036.6	2,186.1	2,075.1
Selling, general, and administrative	1,834.8	1,556.2	1,320.4
Cost of goods sold	362.3	180.0	202.5
Cost of collaboration and contract manufacturing	419.9	254.1	194.6
	5,653.6	4,176.4	3,792.6
Income from operations	2,209.8	2,534.4	2,079.6
Other income (expense):			
Other income (expense), net	249.5	47.3	24.0
Interest expense	(30.2)	(28.2)	(25.1)
	219.3	19.1	(1.1)
Income before income taxes	2,429.1	2,553.5	2,078.5
Income tax expense	(313.3)	(109.1)	(880.0)
Net income	$ 2,115.8	$ 2,444.4	$ 1,198.5
Net income per share - basic	$ 19.38	$ 22.65	$ 11.27
Net income per share - diluted	$ 18.46	$ 21.29	$ 10.34
Weighted average shares outstanding - basic	109.2	107.9	106.3
Weighted average shares outstanding - diluted	114.6	114.8	115.9
Statements of Comprehensive Income			
Net income	$ 2,115.8	$ 2,444.4	$ 1,198.5
Other comprehensive income (loss), net of tax:			
Unrealized gain (loss) on marketable securities	35.9	(7.0)	12.7
Unrealized (loss) gain on cash flow hedges	(2.5)	0.7	0.8
Comprehensive income	$ 2,149.2	$ 2,438.1	$ 1,212.0

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

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2019, 2018, and 2017
(In millions)

	Class A 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, 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 for equity awards granted under long-term incentive plans	—	—	2.4	—	240.6	—	—	—	—	240.6
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.8)	—	(301.7)	—	—	—	—	(301.7)
Issuance of Common Stock for 401(k) Savings Plan	—	—	—	—	19.4	—	—	—	—	19.4
Stock-based compensation charges	—	—	—	—	524.6	—	—	—	—	524.6
Net income	—	—	—	—	—	1,198.5	—	—	—	1,198.5
Other comprehensive income, net of tax	—	—	—	—	—	—	13.4	—	—	13.4
Balance, December 31, 2017	1.9	—	109.5	0.1	3,512.9	2,946.7	0.6	(3.8)	(316.2)	6,144.1
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	2.0	—	114.2	—	—	—	—	114.2
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.5)	—	(187.2)	—	—	—	—	(187.2)
Issuance of Common Stock for 401(k) Savings Plan	—	—	0.1	—	26.9	—	—	—	—	26.9
Repurchases of Common Stock	—	—	—	—	—	—	—	(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	—	111.1	0.1	3,911.6	5,254.3	(12.3)	(4.0)	(396.4)	8,757.3

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY *(continued)*

	Class A 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	
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	2.6	—	213.2	—	—	—	—	213.2
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.5)	—	(188.0)	—	—	—	—	(188.0)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	24.9	—	—	0.1	13.2	38.1
Repurchases of Common Stock	—	—	—	—	—	—	—	(1.0)	(356.7)	(356.7)
Conversion of Class A Stock to Common Stock	(0.1)	—	0.1	—	—	—	—	—	—	—
Stock-based compensation charges	—	—	—	—	466.9	—	—	—	—	466.9
Adjustment upon adoption of new accounting standard	—	—	—	—	—	9.7	—	—	—	9.7
Net income	—	—	—	—	—	2,115.8	—	—	—	2,115.8
Other comprehensive income, net of tax	—	—	—	—	—	—	33.4	—	—	33.4
Balance, December 31, 2019	1.8	—	113.3	$ 0.1	$ 4,428.6	$ 7,379.8	$ 21.1	(4.9)	$ (739.9)	$ 11,089.7

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

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities:			
Net income	$ 2,115.8	$ 2,444.4	$ 1,198.5
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	210.3	148.2	145.5
Non-cash compensation expense	464.3	427.4	507.3
Other non-cash items, net	(29.3)	12.1	63.5
Deferred taxes	(130.6)	(140.0)	318.8
Changes in assets and liabilities:			
Increase in Sanofi, Bayer, and trade accounts receivable	(473.1)	(268.9)	(362.7)
Increase in inventories	(335.5)	(387.9)	(314.2)
Increase in prepaid expenses and other assets	(130.4)	(55.7)	(113.3)
Increase (decrease) in deferred revenue	294.0	(194.5)	(113.1)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	444.5	210.0	(23.2)
Total adjustments	314.2	(249.3)	108.6
Net cash provided by operating activities	2,430.0	2,195.1	1,307.1
Cash flows from investing activities:			
Purchases of marketable and other securities	(3,202.4)	(1,845.5)	(1,277.2)
Sales or maturities of marketable securities	1,604.2	775.6	544.6
Capital expenditures	(429.6)	(383.1)	(272.6)
Other	—	(10.0)	—
Net cash used in investing activities	(2,027.8)	(1,463.0)	(1,005.2)
Cash flows from financing activities:			
Proceeds in connection with finance lease liabilities	—	—	57.0
Payments in connection with finance lease liabilities	—	—	(19.9)
Proceeds from issuance of Common Stock	211.8	114.5	240.2
Payments in connection with Common Stock tendered for employee tax obligations	(188.0)	(187.2)	(301.7)
Repurchases of Common Stock	(275.9)	(4.4)	—
Net cash used in financing activities	(252.1)	(77.1)	(24.4)
Net increase in cash, cash equivalents, and restricted cash	150.1	655.0	277.5
Cash, cash equivalents, and restricted cash at beginning of period	1,480.2	825.2	547.7
Cash, cash equivalents, and restricted cash at end of period	$ 1,630.3	$ 1,480.2	$ 825.2
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	$ 25.0	$ 22.3	$ 18.7
Cash paid for income taxes	$ 342.3	$ 205.6	$ 754.8

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

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, pain, infectious diseases, and rare diseases. The Company's products that have received marketing approval, which are currently marketed by us and/or our collaborators, consist of EYLEA® (aflibercept), Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), 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") 842, *Leases*, on January 1, 2019 (the "effective date") and used the effective date as our date of initial application. See Note 11. The new standard requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability for future lease payments and a right-of-use asset representing its right to use the underlying asset over the lease term. We elected the practical expedients upon transition, which permitted companies to not reassess lease identification, classification, and initial direct costs under the new standard for leases that commenced prior to the effective date. Upon adoption of the new standard, we recognized right-of-use assets of $33.2 million related to operating leases as of January 1, 2019. The impact of adopting the standard for the facilities that we had historically applied build-to-suit and capital lease accounting was not material to our Consolidated Financial Statements. Prior period amounts have not been adjusted in connection with the adoption of this standard.

We adopted 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 were not adjusted in connection with the adoption of this standard. We also adopted Accounting Standards Update ("ASU") 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*, as of January 1, 2018. 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.

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.

Concentration of Credit Risk

Financial instruments which potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents, certain investments, 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, 2019 and 2018, three individual customers accounted for 97% and 99%, respectively, of the Company's net trade accounts receivable balances. The Company has contractual payment terms with each of its customers, and the Company monitors its customers' financial performance and credit worthiness so that it can properly assess and respond to any changes in their credit profile. As of December 31, 2019 and 2018, there were no reserves against trade accounts receivable. In addition, during the years ended December 31, 2019, 2018, and 2017, the Company did not recognize any charges for write-offs of trade accounts receivable.

Significant Accounting Policies

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.

Debt and Equity 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-for-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 within Other income (expense), net.

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

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. In addition, the Company records accounts receivable arising from its collaboration and licensing agreements. The Company monitors the financial performance and credit worthiness of its counterparties so that it can properly assess and respond to changes in their credit profile. The Company provides reserves against receivables for estimated losses, if any, that may result from a counterparty'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 net 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.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated 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 remaining 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

Product Revenue

Product revenue consists of U.S. net product 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 take physical delivery of product. For EYLEA and Libtayo, the distributors and specialty pharmacies 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 payor 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.

Rebates, Chargebacks, and Discounts: The Company estimates reductions to product sales for Medicaid and Veterans' Administration ("VA") programs as well as certain other qualifying federal and state government programs, and for other programs, including group purchasing organizations. Based upon the Company's contracts with government agencies and other organizations, statutorily-defined discounts applicable to government-funded programs, historical experience, and estimated payor 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, and others (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.

Other Sales-Related Deductions: The Company estimates other sales-related deductions offered to customers based on written contracts. The Company estimates and records other sales-related deductions generally based on gross sales.

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.

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. During the first quarter of 2018, we adopted ASC 606, *Revenue from Contracts with Customers*. Under ASC 606, 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, reimbursements for development activities, as well as reimbursements 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 proportionately as we recognize our expenses. We recognized collaboration revenue for non-refundable up-front payments, development milestones, and payments for development activities, for which we used an input method, of $497.6 million and $837.7 million for the years ended December 31, 2019 and 2018, respectively.

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 revenue is deferred until the 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.

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, contract research organizations ("CROs"), or other third-party service providers are expected to provide services. 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.

Stock-based Compensation

The Company recognizes stock-based compensation expense for equity grants 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 fair value of stock option awards are estimated using the Black-Scholes model. 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 fair value of performance-based restricted stock units which are subject to vesting based on the Company’s attainment of pre-established performance goals is estimated using a Monte Carlo simulation. The probability of the number of actual shares expected to be earned is considered in the grant-date valuation, and therefore, stock-based compensation expense is not adjusted at the vesting date to reflect the actual number of shares earned.

Income Taxes

The provision for income taxes includes U.S. federal, state, local, and foreign taxes. Income taxes are accounted for under the liability method. 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, are recognized on 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

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

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 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 and (ii) Common Stock to be issued upon the achievement of certain market conditions, which are included under the "treasury stock method" when dilutive.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the current other-than-temporary impairment model. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We do not expect the adoption of this standard to have a significant impact on our financial statements or internal controls.

2. Product Sales

Net product sales consist of the following:

	Year Ended December 31,		
Net Product Sales in the United States	**2019**	**2018**	**2017**
EYLEA	$ 4,644.2	$ 4,076.7	$ 3,701.9
Libtayo	175.7	14.8	—
ARCALYST	14.5	14.7	16.6
	$ 4,834.4	$ 4,106.2	$ 3,718.5

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, 2019, 2018, and 2017. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Year Ended December 31,		
	2019	**2018**	**2017**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	57%	56%	51%
McKesson Corporation	33%	36%	29%
Curascript SD Specialty Distribution, a subsidiary of Express Scripts	**	**	19%

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

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

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 sales-related deductions for the years ended December 31, 2019, 2018, and 2017.

	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
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
Provisions	423.2	242.9	61.8	727.9
Credits/payments	(384.0)	(238.5)	(40.7)	(663.2)
Balance as of December 31, 2019	$ 80.3	$ 46.4	$ 29.4	$ 156.1

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 23,350,365 shares of our Common Stock as of December 31, 2019, a portion of which was purchased in connection with the companies' antibody collaboration described below. See Note 12 for a description of the investor agreement between us and Sanofi.

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

The collaboration revenue we earned from Sanofi is detailed below:

	Year Ended December 31,		
Sanofi Collaboration Revenue	**2019**	**2018**	**2017**
Antibody:			
Reimbursement of research and development expenses	$ 277.7	$ 265.3	$ 508.4
Reimbursement of commercialization-related expenses	479.9	417.2	368.8
Reimbursement for manufacturing of commercial supplies	206.7	127.6	35.1
Regeneron's share of profits (losses) in connection with commercialization of antibodies	209.3	(227.0)	(442.6)
Other	(1.5)	(24.1)	84.0
Total Antibody	1,172.1	559.0	553.7
Immuno-oncology:			
Reimbursement of research and development expenses	163.0	311.8	240.0
Reimbursement of commercialization-related expenses	10.3	8.9	7.0
Amounts recognized in connection with up-front payments received	92.7	243.8	80.0
Other	(11.3)	(12.4)	(3.5)
Total Immuno-oncology	254.7	552.1	323.5
	$ 1,426.8	$ 1,111.1	$ 877.2

Antibody

In 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 funded $130.0 million of the Company's research activities in 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 (*i.e.*, 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 $46.0 million, $47.7 million, and $91.8 million in 2019, 2018, and 2017, respectively, its share of antibody development expenses that Sanofi incurred related to Dupixent, Praluent, and Kevzara. All other agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi. We are 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, we are only required to apply 10% of our 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 $2.990 billion as of December 31, 2019.

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 2019, Sanofi elected to sell, and we elected to purchase (in cash), 93,286 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 $29.4 million, as Treasury Stock during 2019. During 2018, the cost of shares of the Company's Common Stock that we elected to purchase from Sanofi (in cash) in connection with Sanofi's funding obligation for Dupilumab/REGN3500 Eligible Investments was not material.

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-commercialize such products. The Company has exercised its option to co-commercialize Dupixent, Praluent, and Kevzara in the United States. While we are not currently co-commercializing these antibodies outside the United States, we have recently exercised our option to co-commercialize Dupixent in certain countries outside the United States. We currently anticipate commencing co-commercialization of Dupixent outside the United States at the end of 2020. 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 commercialization-related expenses" in the table above represents reimbursement of internal and external costs in connection with commercializing Dupixent, Praluent, and Kevzara. 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 profits or losses in connection with the companies commercializing Dupixent, Praluent, and Kevzara, within Sanofi collaboration revenue.

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. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse Sanofi for development costs out of any future profits from collaboration products will terminate.

In December 2019, we and Sanofi announced our intent to restructure the Antibody Collaboration for Kevzara and Praluent and enter into a royalty-based arrangement. Under the proposed terms of the agreement, Sanofi is expected to gain sole global rights to Kevzara and sole rights to Praluent outside of the United States. Regeneron is expected to gain sole U.S. rights to Praluent. Under the proposed terms, each party will be solely responsible for funding development and commercialization expenses in their respective territories. In the fourth quarter of 2019, we recorded a $35.2 million charge related to employee separation costs, as the Company has eliminated certain commercialization activities and related headcount in connection with the proposed restructuring of the antibody agreement with Sanofi. The proposed agreement with Sanofi to restructure the antibody agreement, which is expected to be finalized in the first quarter of 2020, will not impact Dupixent and REGN3500 as the companies will continue to collaborate on these antibodies under the terms of the License and Collaboration Agreement.

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. 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; therefore, 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, 2019, and therefore has not been included in the transaction price.

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

The following table summarizes contract balances in connection with the Company's Antibody Collaboration with Sanofi:

	As of December 31,	
	2019	**2018**
Accounts receivable	$ 272.7	$ 138.2
Deferred revenue	$ 337.2	$ 236.1

Significant changes in deferred revenue balances are as follows:

	Year Ended December 31, 2019
Increase due to shipments of commercial supplies to Sanofi	$ 335.7
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (240.4)

Immuno-Oncology

In 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 billion ("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 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 bispecific 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 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 with respect to the BCMAxCD3 Program and MUC16xCD3 Program. We are obligated to reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates from our share of future profits from commercialized IO Collaboration products. However, the Company is only required to apply 10% of its share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. The Company's contingent reimbursement obligation to Sanofi under the IO Collaboration was approximately $75 million as of December 31, 2019.

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when (i) clinical proof-of-concept is established, (ii) the applicable Program Costs Cap is reached, or (iii) 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, we 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 global commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) we 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.

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. 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 execution of the IO License and Collaboration Agreement in 2015, Sanofi made a $375.0 million non-refundable up-front payment to the Company. Under the terms of the IO License and Collaboration Agreement, the parties are co-developing and co-commercializing 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 and commercialization 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 the Libtayo development and Dupilumab/REGN3500 Eligible Investments by selling up to an aggregate of 1,400,000 shares (of which 869,828 currently remains available) 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. Refer to Note 18 for details regarding shares Sanofi elected to sell, and we elected to purchase (by issuing a credit towards the amount owed by Sanofi) to satisfy Sanofi's funding obligation related to Libtayo development costs and refer to the "*Antibody*" section above for a description of share transactions related to Dupilumab/REGN3500 Eligible Investments.

The Company has principal control over the development of Libtayo and leads commercialization activities in the United States (see Note 2 for related product sales information), while Sanofi leads commercialization activities outside of the United States and the parties equally share profits and losses from worldwide sales. Consequently, in 2019, we recorded $78.2 million, within Cost of goods sold, related to our obligation to pay Sanofi its share of Libtayo U.S. gross profits; such amounts were not material in 2018. As it relates to the commercialization of Libtayo outside of the United States, we recognize our share of profits and losses within Sanofi collaboration revenue.

In September 2018, the FDA approved Libtayo for the treatment of patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC"), and Sanofi exercised its option to co-commercialize 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, 2019, 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, and royalties

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

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-commercialize 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.

"Amounts recognized in connection with up-front payments received" in the Sanofi Collaboration Revenue table above includes recognition of deferred revenue from (i) the aggregate up-front payments received during 2015 and (ii) amounts received in connection with the termination of the 2015 IO Discovery Agreement (as described above). During 2018, we reduced our estimate of the total research and development costs expected to complete the contract, including in connection with the termination of the 2015 IO Discovery Agreement, and, as result, a cumulative catch-up adjustment of $135.0 million was recognized for the year ended December 31, 2018.

The following table summarizes contract balances in connection with the Company's IO Collaboration with Sanofi:

	As of December 31,	
	2019	**2018**
Accounts receivable, net	$ (16.7)	$ 77.9
Deferred revenue	$ 568.0	$ 289.9

Significant changes in deferred revenue balances are as follows:

	Year Ended December 31, 2019
Increase as a result of payment received from Sanofi in connection with the termination of the 2015 IO Discovery Agreement	$ 415.9
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (92.7)
Revenue recognized that was added to deferred revenue during the period	$ (48.4)

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, 2019 was $1.138 billion. This amount is expected to be recognized as revenue over the remaining period in which the Company is obligated to satisfy its performance obligation in connection with performing development activities.

(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 were previously terminated):

	Year Ended December 31,		
Bayer EYLEA Collaboration Revenue	**2019**	**2018**	**2017**
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 1,091.4	$ 992.3	$ 802.3
Reimbursement of EYLEA development expenses	23.0	11.2	13.3
Other	74.4	73.6	58.7
	$ 1,188.8	$ 1,077.1	$ 874.3

In 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 through 2021, and thereafter, the companies will share equally in profits and losses from the sales of EYLEA. 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 $270 million as of December 31, 2019.

c. Teva

In 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 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. The Company is also responsible for the manufacture and supply of fasinumab globally.

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

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

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, 2019, 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 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 $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 $206.5 million, $244.6 million, and $221.5 million of revenue in 2019, 2018, and 2017, respectively, in connection with the Teva Collaboration Agreement.

The following table summarizes contract balances in connection with the Teva Collaboration Agreement:

	As of December 31,	
	2019	2018
Accounts receivable (recorded within Prepaid expenses and other current assets)	$ 21.2	$ 28.8
Deferred revenue	$ 114.4	$ 194.5

Significant changes in deferred revenue balances are as follows:

	Year Ended December 31, 2019
Revenue recognized that was included in deferred revenue at the beginning of the period	$ (82.1)

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, 2019 was $267.1 million. This amount is expected to be recognized as revenue over the remaining period in which the Company is obligated to satisfy its performance obligation in connection with performing development activities.

d. Alnylam

In April 2019, the Company and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference ("RNAi") therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. The collaboration is governed by a Master Collaboration Agreement (the "Master Agreement") (including the form of a License Agreement and a Co-Commercialization Collaboration Agreement). Under the terms of the Master Agreement, we made an up-front payment of $400.0 million to Alnylam, which was recorded in Research and development expense during the second quarter of 2019. For each program, we will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to $200.0 million in clinical proof-of-principle milestones for eye or CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Commercialization Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain

situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more INDs (or their equivalent in certain other countries) for programs in the eye and CNS.

In connection with the collaboration, we and Alnylam also entered into a Stock Purchase Agreement. Pursuant to the terms of the Stock Purchase Agreement, we purchased shares of Alnylam common stock for aggregate cash consideration of $400.0 million.

In August 2019, the parties entered into a Co-Commercialization Collaboration Agreement for a silencing RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic and a fully human monoclonal antibody targeting C5 being developed by us, with us as the licensee. The C5 siRNA Co-Commercialization Collaboration Agreement is consistent with the financial terms contained in the form of the existing Co-Commercialization Collaboration Agreement with Alnylam and the parties will share in development expenses equally. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on our potential future net sales of the combination product only subject to customary reductions, as well as up to $325.0 million in commercial milestones.

e. 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.

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, 2019 and 2018 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:

	Amortized	Unrealized		Fair
As of December 31, 2019	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 3,960.5	$ 27.8	$ (0.2)	$ 3,988.1
U.S. government and government agency obligations	54.3	0.2	(0.1)	54.4
Sovereign bonds	26.9	0.4	—	27.3
Commercial paper	92.3	—	—	92.3
Certificates of deposit	72.3	0.1	—	72.4
	$ 4,206.3	$ 28.5	$ (0.3)	$ 4,234.5
As of December 31, 2018				
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

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, 2019 mature at various dates through December 2024. The fair values of available-for-sale debt security investments by contractual maturity consist of the following:

	As of December 31,	
	2019	**2018**
Maturities within one year	$ 1,596.5	$ 1,342.2
Maturities after one year through five years	2,638.0	1,667.0
	$ 4,234.5	$ 3,009.2

(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, 2019	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 257.2	$ (0.2)	$ 41.1	$ —	$ 298.3	$ (0.2)
U.S. government and government agency obligations	17.3	(0.1)	2.0	—	19.3	(0.1)
	$ 274.5	$ (0.3)	$ 43.1	$ —	$ 317.6	$ (0.3)
As of December 31, 2018						
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)

There were no realized losses on sales of marketable securities, and realized gains were not material, for the year ended December 31, 2019. Realized gains and losses on sales of marketable securities were not material for the years ended December 31, 2018 and 2017.

With respect to marketable securities, for the years ended December 31, 2019, 2018, and 2017, amounts reclassified from Accumulated other comprehensive income (loss) into Other income (expense), net were related to realized gains and losses on sales of securities (as described above).

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

5. Fair Value Measurements

The table below summarizes the Company's assets which are measured at fair value on a recurring basis. The following fair value hierarchy is used to classify assets, based on inputs to valuation techniques utilized to measure fair value:

- Level 1 - Quoted prices in active markets for identical assets
- Level 2 - Significant other observable inputs, such as 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
- Level 3 - Significant other unobservable inputs

		Fair Value Measurements at Reporting Date	
As of December 31, 2019	**Fair Value**	**Level 1**	**Level 2**
Available-for-sale debt securities:			
Corporate bonds	$ 3,988.1	—	$ 3,988.1
U.S. government and government agency obligations	54.4	—	54.4
Sovereign bonds	27.3	—	27.3
Commercial paper	92.3	—	92.3
Certificates of deposit	72.4	—	72.4
Equity securities (unrestricted)	61.6	$ 61.6	—
Equity securities (restricted)	557.2	557.2	—
	$ 4,853.3	$ 618.8	$ 4,234.5
As of December 31, 2018			
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

The Company held certain restricted equity securities as of December 31, 2019, including its investment in Alnylam (see Note 3), which are subject to transfer restrictions that expire at various dates through 2023.

The Company adopted ASU 2016-01 during the first quarter of 2018 (see Note 1); as a result, we recorded $118.3 million of net unrealized gains and $41.9 million of net unrealized losses on equity securities in Other income (expense), net for the years ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2017, we recorded net unrealized gains of $14.7 million on equity securities in Other comprehensive income (loss).

In addition to the investments summarized in the table above, as of December 31, 2019 and 2018, the Company had $55.6 million and $45.5 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets.

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

6. Inventories

Inventories consist of the following:

	As of December 31,	
	2019	2018
Raw materials	$ 216.3	$ 226.8
Work-in-process	727.7	571.1
Finished goods	70.6	24.4
Deferred costs	400.9	328.9
	$ 1,415.5	$ 1,151.2

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred (see Note 1 for a further description of the related accounting policy). For the years ended December 31, 2019, 2018, and 2017, Cost of goods sold included inventory write-downs and reserves of $73.8 million, $12.5 million, and $20.9 million, respectively.

7. Property, Plant, and Equipment

Property, plant, and equipment consists of the following:

	As of December 31,	
	2019	2018
Land	$ 230.8	$ 199.0
Building and improvements	1,683.4	1,507.2
Leasehold improvements	97.6	97.0
Construction in progress	644.8	469.6
Laboratory equipment	850.7	773.7
Computer equipment and software	183.7	145.8
Furniture, office equipment, and other	121.8	112.2
	3,812.8	3,304.5
Less, accumulated depreciation and amortization	(922.4)	(728.7)
	$ 2,890.4	$ 2,575.8

Property, plant, and equipment in the table above includes leased property under the Company's finance lease at its Tarrytown, New York facility. See Note 11.

Depreciation and amortization expense (including as it relates to the Company's finance lease) on property, plant, and equipment amounted to $205.2 million, $144.1 million, and $142.2 million for the years ended December 31, 2019, 2018, and 2017, respectively.

As of December 31, 2019 and 2018, $2,117.6 million and $1,813.8 million, respectively, of the Company's net property, plant, and equipment was located in the United States and $772.8 million and $762.0 million, respectively, was located in Europe (primarily in Ireland).

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

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2019	2018
Accrued payroll and related costs	$ 344.4	$ 261.8
Accrued clinical expenses	142.7	142.2
Accrued sales-related charges, deductions, and royalties	249.0	182.7
Income taxes payable	49.4	20.8
Other accrued expenses and liabilities	301.3	164.6
	$ 1,086.8	$ 772.1

9. Deferred Revenue

Deferred revenue consists of the following:

	As of December 31,	
	2019	2018
Current portion:		
Received or receivable from Sanofi (see Note 3a)	$ 395.5	$ 246.7
Received or receivable from Bayer (see Note 3b)	49.2	44.4
Received or receivable from Teva (see Note 3c)	89.5	92.5
Other	57.5	68.9
	$ 591.7	$ 452.5
Noncurrent portion:		
Received or receivable from Sanofi (see Note 3a)	$ 509.7	$ 279.3
Received or receivable from Bayer (see Note 3b)	73.8	45.1
Received or receivable from Teva (see Note 3c)	24.9	102.0
Other	10.6	37.8
	$ 619.0	$ 464.2

10. 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, 2019.

The Credit Agreement contains financial and operating covenants. The Company was in compliance with all covenants of the Credit Facility as of December 31, 2019.

11. Commitments and Contingencies

See Note 16 for disclosures related to legal contingencies.

a. Leases

We conduct certain of our research, development, and administrative activities at leased facilities. We also lease certain warehouses and vehicles. As described in Note 1, during the first quarter of 2019, we adopted ASC 842, *Leases*.

We determine if an arrangement is a lease considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Our lease terms may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. We account for lease components (*e.g.*, rental payments) separately from non-lease components (*e.g.*, common area maintenance costs).

Right-of-use assets and lease liabilities are recognized at lease commencement date based on the present value of lease payments over the lease term, unless there is a transfer of title or purchase option we are reasonably certain to exercise. For leases where an implicit rate is not readily determinable, we use our incremental borrowing rate based on information available at the lease commencement date to determine the present value of future lease payments. Lease expense for operating leases is recognized on a straight-line basis over the expected lease term.

Operating leases

Amounts recognized in our Consolidated Balance Sheets and Statements of Operations included in this report associated with operating leases were not material. Operating lease right-of-use assets are included within Other noncurrent assets, and lease liabilities are included in Accrued expenses and other current liabilities and Other noncurrent liabilities.

Finance leases

In March 2017, we entered into a Participation Agreement with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively, the "Lease Participants"). In March 2017, we also entered into a Lease and Remedies Agreement with BAL, pursuant to which we have leased laboratory and office facilities in Tarrytown, New York (the "Facility") for a five-year term. The Participation Agreement, the Lease and Remedies Agreement, and certain other related agreements were amended and restated in May 2019, among other things, to revise certain covenants, representations and warranties, and events of default to be substantially similar to those set forth in the agreement governing the Company's revolving credit facility (as so amended and restated, the "Participation Agreement" and the "Lease," respectively). 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 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 Lease 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 Lease 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.

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

Prior to January 1, 2019, for certain of the premises under the Lease we were deemed, in substance, to be the owner of the buildings (collectively, the "Build-to-Suit Buildings"). Upon the adoption of ASC 842, the classification of the Build-to-Suit Buildings, for which the construction period had been completed, was reassessed and, consequently, they were derecognized and recognized as a finance lease. These premises, along with the other premises under the Lease, are classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised.

The agreements governing the Lease financing contain financial and operating covenants. The Company was in compliance with all such covenants as of December 31, 2019.

Amounts recognized in the Consolidated Balance Sheet related to the Lease are included in the table below. Other than the Lease described above, we had no leases accounted for as finance leases as of December 31, 2019.

	Classification	December 31, 2019
Finance lease right-of-use assets	Property, plant, and equipment, net[(1)]	$ 660.1
Finance lease liabilities	Finance lease liabilities (noncurrent)	$ 713.9

[(1)] Finance lease right-of-use assets are recorded net of accumulated amortization of $76.1 million as of December 31, 2019.

As of December 31, 2018, property, plant, and equipment, at cost, included $723.9 million of leased property under the Lease. Accumulated amortization related to these assets amounted to $61.7 million as of December 31, 2018.

Finance lease costs consist of the following:

	Year Ended December 31, 2019
Amortization of right-of-use assets	$ 14.4
Interest on lease liabilities	27.6
	$ 42.0

Other information related to our finance lease includes the following:

	December 31, 2019
Remaining lease term (in years)	2.17
Discount rate	3.05%

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

Supplemental information

The following is a maturity analysis of our lease liabilities as of December 31, 2019:

	Operating Leases	Finance Leases
2020	$ 7.6	$ 22.2
2021	6.6	21.9
2022	3.3	725.4
2023	2.0	—
2024	2.3	—
Thereafter	4.3	—
Total undiscounted lease payments	26.1	769.5
Imputed interest	(2.5)	(50.1)
Debt financing costs	—	(5.5)
Total lease liabilities	$ 23.6	$ 713.9

As of December 31, 2018, the estimated future minimum noncancelable lease commitments, excluding the purchase price we would be obligated to pay if we were to exercise our option to purchase the Facility, were as follows:

	Operating Leases	Capital and Facility Lease Obligations
2019	$ 10.4	$ 26.4
2020	3.8	28.4
2021	3.4	27.9
2022	2.2	7.0
2023	1.5	—
Thereafter	4.1	—
	$ 25.4	$ 89.7

b. Research Collaboration and Licensing Agreements

As part of our research and development efforts, we enter 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 out of the respective collaboration's profits, if they are sufficient for that purpose. See Note 3 for a more detailed description of collaboration agreements.

For the years ended December 31, 2019, 2018, and 2017, the Company recorded royalty expense in Cost of goods sold and Cost of collaboration and contract manufacturing of $54.2 million, $36.7 million, and $30.8 million, respectively, based on product sales of commercial products under various licensing agreements.

12. 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.

Share Repurchase Program

In November 2019, our board of directors authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. The share repurchase program permits the Company to effect repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. Repurchases may be made from time to time at management’s discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. The program has no time limit and can be discontinued at any time. During 2019, we repurchased 722,596 shares of Common Stock under the program and recorded the cost of the shares received, or $254.0 million, as Treasury Stock. There can be no assurance as to the timing or number of shares of any repurchases in the future.

Arrangements with Collaborators

In 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 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, 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 869,828 shares remain available to be sold as of December 31, 2019) of the Company's Common Stock held by Sanofi 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, 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.

13. 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 and approved by the Company's shareholders in 2017, at which time 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, which may be time- or performance-based), and (d) other awards. Any award granted may (but is not required to) be subject to vesting based on the attainment by the Company of performance goals pre-established by the Committee.

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.

REGENERON PHARMACEUTICALS, INC.
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As of December 31, 2019, there were 9,546,628 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.

a. Stock Options

Transactions involving stock option awards during 2019 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, 2018	28,279,696	$ 319.28		
2019: Granted	3,271,222	$ 366.65		
Forfeited	(576,806)	$ 395.88		
Expired	(300,581)	$ 460.37		
Exercised	(2,064,254)	$ 103.51		
Outstanding as of December 31, 2019	28,609,277	$ 337.24	6.17	$ 1,805.9
Vested and expected to vest as of December 31, 2019	27,524,704	$ 335.73	6.06	$ 1,800.5
Exercisable as of December 31, 2019	19,291,335	$ 318.15	4.90	$ 1,763.9

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 2019, 2018, and 2017 was $558.9 million, $510.6 million, and $735.6 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, 2019, 2018, and 2017. 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
2019:			
Exercise price equal to Market Price	3,271,222	$ 366.65	$ 100.80
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

For the years ended December 31, 2019, 2018, and 2017, the Company recognized $422.8 million, $421.8 million, and $492.8 million, respectively, of non-cash stock-based compensation expense related to stock option awards (net of amounts capitalized as inventory of $2.4 million, $17.1 million, and $16.8 million, respectively). As of December 31, 2019, there was $521.9 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.

(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 2019, 2018, and 2017.

	2019	2018	2017
Expected volatility	28%	29%	31%
Expected lives from grant date	5.0 years	4.9 years	5.1 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	1.74%	2.69%	2.16%

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 (including performance-based restricted stock units) (collectively, "restricted stock") during 2019 is summarized below. As described in Note 1, the fair value of performance-based restricted stock units is estimated using a Monte Carlo simulation.

		Number of Shares/Units	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2018		472,630	$ 386.10
2019:	Granted	698,103	$ 356.33
	Vested	(3,090)	$ 406.65
	Forfeited/Cancelled	(5,857)	$ 385.90
Balance as of December 31, 2019		1,161,786	$ 368.16

The Company recognized non-cash stock-based compensation expense from restricted stock of $41.5 million, $5.6 million, and $14.5 million in 2019, 2018, and 2017, respectively (net of amounts capitalized as inventory, which were not material for each of the three years). As of December 31, 2019, there was $274.6 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 3.4 years.

14. 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 $38.1 million, $27.0 million, and $19.6 million of Contribution expense in 2019, 2018, and 2017, respectively.

The Company also maintains additional employee savings plans outside of the United States, which cover eligible employees. Expenses recognized by the Company related to contributions to such plans were not material during 2019, 2018, and 2017.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
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15. 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,		
	2019	2018	2017
United States	$ 2,011.2	$ 2,151.7	$ 1,964.7
Foreign	417.9	401.8	113.8
	$ 2,429.1	$ 2,553.5	$ 2,078.5

Components of income tax expense consist of the following:

	Year Ended December 31,		
	2019	2018	2017
Current:			
Federal	$ 444.6	$ 223.7	$ 560.3
State	1.9	4.8	(4.1)
Foreign	(2.6)	20.6	4.8
Total current tax expense	443.9	249.1	561.0
Deferred:			
Federal	(132.0)	687.6	317.1
State	(1.7)	(1.9)	(1.3)
Foreign	3.1	(825.7)	3.2
Total deferred tax (benefit) expense	(130.6)	(140.0)	319.0
	$ 313.3	$ 109.1	$ 880.0

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,		
	2019	2018	2017
U.S. federal statutory tax rate	21.0 %	21.0 %	35.0 %
Income tax credits	(4.6)	(2.6)	(1.3)
Stock-based compensation	(2.5)	(2.5)	(9.0)
Foreign-derived intangible income deduction	(1.6)	(1.0)	—
Taxation of non-U.S. operations	(1.0)	(1.9)	0.7
Non-deductible Branded Prescription Drug Fee	0.7	0.6	1.7
Sale of non-inventory related assets between foreign subsidiaries	—	(6.3)	—
Impact of change in U.S. corporate tax rate (the Act)	—	(2.7)	15.7
Domestic production activities deduction	—	—	(2.6)
Other permanent differences	0.9	(0.3)	2.1
Effective income tax rate	12.9 %	4.3 %	42.3 %

The difference between the U.S. federal statutory rate and the Company's effective tax rate for each of the three years ended December 31, 2019, 2018, and 2017 is summarized in the table above. In 2018, the difference between the U.S. federal statutory rate of 21% and the Company's effective tax rate of 4.3% was partly 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). In

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

2017, the difference between the U.S. federal statutory rate of 35% and the Company's effective tax rate of 42.3% was partly impacted by the charge related to the re-measurement of the Company's U.S. net deferred tax assets upon the enactment of the Act (see below).

In December 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 a final 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.

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,	
	2019	**2018**
Deferred tax assets:		
Deferred compensation	$ 519.7	$ 458.2
Fixed assets and intangible assets	192.0	107.8
Accrued expenses	75.9	53.3
Deferred revenue	22.0	20.2
Other	—	33.3
Total deferred tax assets	809.6	672.8
Valuation allowance	(7.0)	—
Deferred tax assets, net of valuation allowance	802.6	672.8
Deferred tax liabilities:		
Other	(11.2)	(2.7)
Net deferred tax assets	$ 791.4	$ 670.1

The Company's 2015 through 2018 federal income tax returns remain open to examination by the IRS. The Company's 2015 and 2016 federal income tax returns are currently under audit by the IRS. In general, the Company's state income tax returns from 2016 to 2018 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 tax credit carryforward position. In general, tax authorities have the ability to review income tax returns in which the statute of limitation has previously expired to adjust the tax credits generated in those years.

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

The following table reconciles the beginning and ending amounts of unrecognized tax benefits. The amount of unrecognized tax benefits that, if settled, would impact the effective tax rate is $210.8 million, $189.5 million, and $146.2 million as of December 31, 2019, 2018, and 2017, respectively.

	2019	2018	2017
Balance as of January 1	$ 189.5	$ 146.2	$ 117.2
Gross increases related to current year tax positions	37.9	51.4	49.0
Gross (decreases) increases related to prior year tax positions	(7.2)	5.6	(5.6)
Gross decreases due to settlements and lapse of statutes of limitations	(9.4)	(13.7)	(14.4)
Balance as of December 31	$ 210.8	$ 189.5	$ 146.2

In 2019, 2018 and 2017, 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.

During 2019, 2018, and 2017, interest expense related to unrecognized tax benefits recorded by the Company was not material. The Company does not believe that it is reasonably possible that the resolution of tax exposures within the next twelve months would have a material impact on its unrecognized tax benefits as of December 31, 2019.

16. 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. As of December 31, 2019 and 2018, the Company had accruals for loss contingencies of $100.0 million and $30.0 million, respectively. 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 and '163 Patent

The Company is a party to patent infringement litigation initiated by the Company involving its European Patent No. 1,360,287 (the "'287 Patent") and its European Patent No. 2,264,163 (the "'163 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 and the '163 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 and the '163 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. Following a trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent, the court issued a final judgment on February 1, 2016, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. On appeal, 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 and subsequently 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). Thereafter, the Supreme Court of the United Kingdom granted Kymab's application for permission to appeal the order made by the Court of Appeal with respect to an issue of validity of the '287 Patent and the '163 Patent and scheduled an oral hearing for February 11–12, 2020. 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 and the Court of Appeal described above. On July 31,

2019, the Company filed an action in the English High Court for a calculation of damages relating to Kymab's infringement of the '287 Patent and the '163 Patent.

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. 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. On January 7, 2019, Merus withdrew its appeal of the '163 Patent in the EPO in connection with the previously reported global settlement.

Proceedings Relating to Praluent (alirocumab) Injection

United States

As described in greater detail below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. (and/or its affiliated entities) against the Company and/or 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 claims of 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. The first jury trial in this litigation (the "First Trial") 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 First 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 in the First Trial, 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 October 5, 2017, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") reversed in part the District Court's decision and remanded for a new trial on the issues of written description and enablement. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious.

On January 3, 2019, the District Court held oral argument in the remanded proceedings 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. On February 8, 2019, the District Court granted the Company and the Sanofi defendants' motion for judgment on the pleadings, thereby dismissing Amgen's claim of willful infringement. The second jury trial in this litigation (the "Second Trial") was held before the District Court in February 2019 to determine the validity of Amgen's asserted patent claims. On February 25, 2019, the jury returned a verdict in the Second Trial generally in favor of Amgen, finding that two claims of the '165 Patent and one claim of the '741 Patent were not invalid. The jury also found that two claims of the '165 Patent were invalid for lack of adequate written description while rejecting the lack of enablement challenges to those two claims. On August 28, 2019, the District Court ruled as a matter of law that Amgen's asserted patent claims are invalid based on lack of enablement. The District Court also conditionally denied the Company and the Sanofi defendants' motion for a new trial. On October 23, 2019, Amgen filed a notice of appeal of the District Court's decision with the Federal Circuit.

On March 18, 2019, Amgen filed a renewed motion for a permanent injunction to prohibit the Company and the Sanofi defendants from Commercializing Praluent in the United States (a "Permanent Injunction"), and an oral hearing on this motion was held in June 2019. Previously, the Federal Circuit stayed and then vacated a Permanent Injunction granted by the District Court in connection with the First Trial. On August 28, 2019, the District Court dismissed as moot Amgen's renewed motion for a Permanent Injunction.

Europe

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 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. On July 11, 2019, the Düsseldorf Regional Court found that Praluent infringes the '124 Patent and granted an injunction prohibiting the Company and Sanofi's manufacture, sale, and marketing of Praluent in Germany (the "July 11 Decision"). Amgen subsequently enforced the injunction and, as a result, commercialization of Praluent in Germany has been discontinued. On July 12, 2019, the Company and Sanofi appealed the July 11 Decision to the Higher Regional Court of Düsseldorf (the "Higher Regional Court"). An oral hearing on the merits of the appeal to the Higher Regional Court has been scheduled for April 2, 2020. On August 5, 2019 and October 31, 2019, the Higher Regional Court denied the Company and Sanofi's requests for a stay of preliminary enforcement of the July 11 Decision pending the appeal on the merits.

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 and denied the Sanofi parties' request for the provisional compulsory license. On January 16, 2019, the Sanofi parties appealed the FPC's denial of the provisional compulsory license to the Federal Court of Justice (the "FCJ") of Germany. The FCJ held an oral hearing on June 4, 2019 on the appeal of the provisional compulsory license ruling and dismissed the Sanofi parties' appeal. On September 16, 2019, the Sanofi parties filed a brief to withdraw the compulsory license action with the FPC.

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 S.A., 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 rescheduled.

On December 17, 2019, Amgen initiated a lawsuit alleging infringement of the Dutch designation of the '124 Patent in the District Court of The Hague in the Netherlands, against Sanofi-Aventis Netherlands B.V. and Sanofi-Aventis Groupe S.A. The Company has not been named as a defendant in this action. Amgen alleges, among other things, patent infringement based on the production, importation, and commercialization of Praluent (alirocumab) in the Netherlands. Amgen's requests are made on an accelerated basis and include, among other things, a request for a permanent injunction, damages, an order for customer information, a recall order, a destruction order, and an order for costs. A trial has been scheduled for October 30, 2020.

On December 20, 2019, Amgen filed a lawsuit for infringement of the Italian designation of the '124 Patent in the Tribunale di Milano - Enterprise Chamber in Milan, Italy, against Sanofi-Aventis Groupe S.A., Sanofi Chimie, and Sanofi SpA. The Company has not been named as a defendant in this action. Amgen alleges that the production, importation, and commercialization of Praluent

(alirocumab) in Italy infringes the '124 Patent. The writ of summons filed by Amgen seeks, among other things, a declaration of infringement, a permanent injunction, withdrawal of product from the market, and damages.

On December 20, 2019, Amgen also filed a lawsuit alleging infringement of the Spanish designation of the '124 Patent in the Juzgado de lo Mercantil No. 5 (Commercial Court) in Barcelona, Spain, against Sanofi-Aventis, S.A. The Company has not been named as a defendant in this action. Amgen alleges, among other things, patent infringement based on the manufacture, offering for sale, introduction into the market, use, and importation or possession of Praluent (alirocumab) in Spain. Amgen seeks, among other things, a permanent injunction, withdrawal of Praluent from the market, seizure and destruction of Praluent from the market and in storage, and damages in the form of lost profits and costs and expenses.

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 (the "TBA") of the EPO on November 30, 2018. An oral hearing before the TBA has been scheduled for March 24–25, 2020.

Other

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. Following an oral hearing on October 30, 2019, the IPHC affirmed the Tokyo District Court's decision in the infringement proceedings. Sanofi K.K. appealed the IPHC's decision in the infringement proceedings to the Supreme Court of Japan on November 12, 2019. The injunction will remain stayed pending appeal of the IPHC's decision to the Supreme Court of Japan.

Proceedings Relating to Dupixent (dupilumab) Injection

United States

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.

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 February 14, 2019, the PTAB issued final written decisions on the Additional IPR Petitions, invalidating all 17 claims of the '487 Patent as obvious based on one of the Additional IPR Petitions while declining to hold the

challenged claims of the '487 Patent invalid based on the other. In April 2019, the parties filed notices of appeal with the Federal Circuit appealing the PTAB's respective adverse final written decisions on the Additional IPR Petitions.

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. On February 28, 2019, the court granted a joint stipulation by the parties to stay the litigation pending resolution of the appeals of the PTAB's final written decisions on the Additional IPR Petitions discussed above.

Europe

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). The oral hearing before the EPO on the oppositions occurred on February 14–15, 2019, at which the '420 Patent was revoked in its entirety. Immunex filed a notice of appeal of the EPO's decision on May 31, 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. On March 20, 2019, the court issued its Opinion and Order on Claim Construction (the "Claim Construction Order") in the '688 Patent infringement litigation. Pursuant to the Claim Construction Order, on April 1, 2019, the court approved a joint stipulation and entered a partial judgment of noninfringement of the '688 Patent of nine asserted claims. On August 14, 2019, the court issued a second Opinion and Order on Claim Construction concerning the one remaining asserted claim in this litigation. On September 5, 2019, the court entered a stipulated judgment of noninfringement and dismissed with prejudice all of the Novartis Parties' claims of the '688 Patent, finding that the manufacture, use, offer for sale, sale, or importation into the United States of aflibercept does not infringe the claims of the '688 Patent.

On May 14, 2019, the Company filed an IPR in the USPTO seeking a declaration of invalidity of the '688 Patent. On September 26, 2019, in connection with the dismissal of the '688 Patent infringement litigation discussed above, the Company and the Novartis Parties filed a joint motion to terminate the IPR petition, and the PTAB dismissed the IPR petition on October 1, 2019.

Department of Justice Investigations

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.

In September 2019, the Company and Regeneron Healthcare Solutions, Inc., a wholly-owned subsidiary of the Company, each received a civil investigative demand ("CID") from the U.S. Department of Justice pursuant to the federal False Claims Act relating to remuneration paid to physicians in the form of consulting fees, advisory boards, speaker fees, and payment or reimbursement for travel and entertainment allegedly in violation of the federal Anti-Kickback Statute. The CIDs relate to EYLEA, Praluent, Dupixent, ZALTRAP, ARCALYST, and Kevzara and cover the period from January 2015 to the present. The Company is cooperating with this investigation.

17. 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,		
	2019	**2018**	**2017**
Net income - basic and diluted	$ 2,115.8	$ 2,444.4	$ 1,198.5
(Shares in millions)			
Weighted average shares - basic	109.2	107.9	106.3
Effect of dilutive securities:			
Stock options	5.4	6.9	9.1
Restricted stock	—	—	0.5
Weighted average shares - diluted	114.6	114.8	115.9
Net income per share - basic	$ 19.38	$ 22.65	$ 11.27
Net income per share - diluted	$ 18.46	$ 21.29	$ 10.34

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)	**2019**	**2018**	**2017**
Stock options	18.4	14.9	9.2

18. Statement of Cash Flows

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:

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

	December 31,		
	2019	2018	2017
Cash and cash equivalents	$ 1,617.8	$ 1,467.7	$ 812.7
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	$ 1,630.3	$ 1,480.2	$ 825.2

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, 2019, 2018, and 2017 were $133.7 million, $54.5 million, and $41.8 million, respectively, of accrued capital expenditures.

As described in Note 3, during 2019, we purchased (by issuing a credit towards the amount owed by Sanofi) 210,733 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 $73.3 million, as Treasury Stock. During 2018, we purchased (by issuing a credit towards the amount owed by Sanofi) 215,387 shares of our Common Stock from Sanofi, and recorded the cost of the shares received, or $75.8 million, as Treasury Stock.

During 2017, the Company recognized additional lease obligations of $201.2 million in connection with the Company's Tarrytown Lease. No additional amounts were recognized during 2018 or 2019. See Note 11.

19. Unaudited Quarterly Results

Summarized quarterly financial data (unaudited) for the years ended December 31, 2019 and 2018 are set forth in the following tables.

	First Quarter Ended March 31, 2019	Second Quarter Ended June 30, 2019[1]	Third Quarter Ended September 30, 2019	Fourth Quarter Ended December 31, 2019
Revenues	$ 1,711.8	$ 1,933.7	$ 2,048.4	$ 2,169.5
Operating expenses	$ 1,231.8	$ 1,618.1	$ 1,309.9	$ 1,493.8
Net income	$ 461.1	$ 193.1	$ 669.6	$ 792.0
Net income per share - basic	$ 4.23	$ 1.77	$ 6.12	$ 7.25
Net income per share - diluted	$ 3.99	$ 1.68	$ 5.86	$ 6.93

	First Quarter Ended March 31, 2018	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
Operating expenses	$ 944.3	$ 985.8	$ 1,036.6	$ 1,209.7
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

[1] Included in research and development expenses was a $400.0 million up-front payment in connection with the Alnylam collaboration agreement. See Note 3.
[2] Includes impact of a cumulative catch-up adjustment recorded to revenue upon termination of the 2015 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 15.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a description of the common stock, par value $0.001 per share (the "Common Stock"), of Regeneron Pharmaceuticals, Inc. (the "Company") which is the only security of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The following also contains a description of the Class A Stock, par value $0.001 per share (the "Class A Stock"), of the Company, which is not registered pursuant to Section 12 of the Exchange Act but is convertible into shares of Common Stock at any time at the option of the holder. The description of the Class A Stock is necessary to understand the material terms of the Common Stock.

General

The Company is authorized to issue 320,000,000 shares of Common Stock, par value $0.001 per share, of which 108,170,839 shares were issued and outstanding as of January 31, 2020, and 40,000,000 shares of Class A Stock, par value $0.001 per share, of which 1,848,970 shares were issued and outstanding as of January 31, 2020.

The following description summarizes selected information regarding the Common Stock and the Class A Stock, as well as relevant provisions of: (i) the Company's Restated Certificate of Incorporation, as amended, as currently in effect (the "Articles"), (ii) the Company's Amended and Restated By-Laws, as currently in effect (the "By-Laws"), and (iii) the New York Business Corporation Law (the "NYBCL"). The following summary description of the Common Stock and the Class A Stock is qualified in its entirety by, and should be read in conjunction with, the Articles and the By-Laws, copies of which have been filed as exhibits to the Company's periodic reports under the Exchange Act, and the applicable provisions of the NYBCL.

Common Stock and Class A Stock

General. The rights of holders of Common Stock and holders of Class A Stock are identical except for voting rights, conversion rights, and restrictions on transferability.

Voting Rights. The holders of Common Stock are entitled to one vote per share and the holders of Class A Stock are entitled to ten votes per share. Except as otherwise expressly provided by law, holders of common shares have exclusive voting rights on all matters requiring a vote of shareholders. Except as provided by law, the holders of Common Stock and the holders of Class A Stock will vote together as a single class on all matters presented to the shareholders for their vote or approval, including the election of directors. Shareholders are not entitled to vote cumulatively for the election of directors and no class of outstanding common shares acting alone is entitled to elect any directors.

Dividends and Liquidation. Except as described in this paragraph, holders of Common Stock and holders of Class A Stock have an equal right to receive dividends when and if declared by the Company's board of directors out of funds legally available therefor. If a dividend or distribution payable in Class A Stock is made on the Class A Stock, the Company must also make a pro rata and simultaneous dividend or distribution on the Common Stock payable in shares of Common Stock. Conversely, if a dividend or distribution payable in Common Stock is made on the Common Stock, the Company must also make a pro rata and simultaneous dividend or distribution on the Class A Stock payable in shares of Class A Stock. In the event of the Company's liquidation, dissolution, or winding up, holders of Common Stock and Class A Stock are entitled to share equally, share-for-share, in the assets available for distribution after payment of all creditors and the liquidation preferences of any preferred stock.

Optional Conversion Rights. Each share of Class A Stock may, at any time and at the option of the holder, be converted into one fully paid and nonassessable share of Common Stock. Upon conversion, such shares of Common Stock would not be subject to restrictions on transfer that applied to the shares of Class A Stock prior to conversion except to the extent such restrictions are imposed under applicable securities laws. The shares of Common Stock are not convertible into or exchangeable for shares of Class A Stock or any other of the Company's shares or securities.

Other Provisions. Holders of Common Stock and holders of Class A Stock have no preemptive rights to subscribe for any additional securities of any class which the Company may issue and there are no redemption provisions or sinking fund provisions applicable to either such class, nor are the shares of Common Stock or Class A Stock subject to calls or assessments.

Transfer Restrictions. The Class A Stock is subject to certain limitations on transfer that do not apply to the Common Stock.

Listing. The Common Stock is listed on The Nasdaq Global Select Market under the symbol "REGN." The Class A Stock is not listed on a securities exchange.

Transfer Agent and Registrar. The transfer agent and registrar for the Common Stock is American Stock Transfer & Trust Company.

Registration Rights of One of the Company's Shareholders

One of the Company's shareholders, Sanofi, has registration rights. Under the amended and restated investor agreement, as amended (the "Investor Agreement"), between the Company and such shareholder, such shareholder (and certain of its permitted transferees) may request that the Company file registration statements under the Securities Act of 1933 and, upon such request and subject to minimum size and other conditions (such as the lock-up provisions set forth in the Investor Agreement, which are applicable until December 20, 2020), the Company will be required to use its best efforts to effect any such registration. The Company is not required to effect more than three such registrations. The Company is generally obligated to bear the expenses, other than underwriting discounts and sales commissions, of all of these registrations.

Anti-Takeover Effects of Provisions of the Articles, the By-Laws and the NYBCL

Under certain circumstances, certain provisions of the Company's Articles, the Company's By-Laws, and certain provisions of the NYBCL could have the effect of delaying or preventing a change in control of the Company or the Company's 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 the Common Stock.

Among other things, the Articles and the By-Laws provide:

- 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 the 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 the Company's 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 the Company's shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting; and
- 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.

Under the NYBCL, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder," a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon.

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

Notice of Grant of Stock Options and Option Agreement for Time-Based Vesting Option Awards

[OPTIONEE NAME]
[OPTIONEE ADDRESS]

Option Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted a Non-Qualified Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock at $[ ] per share.

The total option price of the shares granted is $[ ].

Shares in each period will become fully vested on the date shown.

Shares	Vest Type	Full Vest	Expiration Date
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]

The Non-Qualified Stock Option expires on [ ]*** (the "Expiration Date").

You and the Company agree that these options are granted under and governed by the terms and conditions of the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Option Agreement, both of which are attached and made a part of this document.

** Options for executive officers will vest in approximately equal annual 25% installments. Full Vest Dates will occur on the first, second, third and fourth anniversaries of the Grant Date.

*** Date to be 10 years from the Grant Date.

REGENERON PHARMACEUTICALS, INC.

Non-Qualified Stock Option

OPTION AGREEMENT
PURSUANT TO
THE AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date of the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Stock Options* (the "Grantee"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Grantee is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the option (the "Option") to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option becomes exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Sections 7(c)(1) (if applicable) and 7(c)(2) of the Plan, the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having an aggregate Fair Market Value (as measured on the date of exercise) equal to the aggregate Option exercise price due upon such exercise. The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall become entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that [(except with respect to retirement on the terms set forth below)][1] the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (the Company and all Subsidiaries shall be referred to herein, collectively, as the "Employer," and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on such Full Vest Dates. Except as otherwise provided below or in the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by or provide services to the Employer and the entire unvested portion of the Option shall be forfeited at such time. [Notwithstanding the preceding sentence, upon the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof), the Option shall continue to vest in installments as provided in the *Notice of Grant of Stock Options* as if the Grantee had continued to be employed by or provide services to the Employer.][2]. For the avoidance of doubt and notwithstanding anything herein or in the *Notice of Grant of Stock Options* to the contrary, any outstanding and unvested portion of the Option shall become fully vested on the date of the Grantee's death. The provisions of this Section 2(b) are subject to (i) the provisions set forth in the *Notice of Grant of Stock*

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[1]Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.
[2]Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

Options or any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* and (ii) the Committee's determination in accordance with Section 7(e) of the Plan.

(c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, but subject to the provisions of any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer if the Grantee's employment with the Employer is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Section 4999 of the Code (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Grantee; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement (as defined in the Company's employee handbook as in effect on the date hereof), or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof) [or the Grantee's death][3], (C) one year after the termination if such termination is due to the Grantee's [death or][4] long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.

(b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Company and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer (other than any such failure resulting from his or her incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Employer, violation of the Employer's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours; (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her

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[3] Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

[4] Not applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred and twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from those which existed immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee; (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which existed immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* that defines "good reason" (or words of like import), as defined under such agreement or plan[; provided, however, that any such definition shall be deemed, solely for purposes of this Agreement, to include as one of the reasons that the employment of Leonard S. Schleifer, M.D., Ph.D. with the Company under the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between Dr. Schleifer and the Company, as in effect from time to time (the "Employment Agreement"), has ended due to Dr. Schleifer's Involuntary Termination (as defined in the Employment Agreement)][5]

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Shareholder. The Grantee shall have no rights as a shareholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates or book-entry registration or registrations for such shares. Except as provided in Section 3(c) of the Plan, no adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

6. Compliance with Law and Regulations. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates or register book entries evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates or the registration of such book entries is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates and book entries bear or be subject to such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be

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[5]Only applicable to Option Agreements for George D. Yancopoulos, M.D., Ph.D.

construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

10. Recoupment. By entering into this Agreement and accepting the award hereunder, the Grantee agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Option and any shares of Common Stock issued pursuant thereto.

Notice of Grant of Stock Options and Option Agreement for Time-Based Vesting Option Awards

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[OPTIONEE NAME]
[OPTIONEE ADDRESS]

Option Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted a Non-Qualified Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock at $[ ] per share.

The total option price of the shares granted is $[ ].

Shares in each period will become fully vested on the date shown.

Shares	Vest Type	Full Vest	Expiration Date
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]
**	On Vest Date	[__/__/__]**	[10 years from Grant Date]

The Non-Qualified Stock Option expires on [ ]*** (the "Expiration Date").

You and the Company agree that these options are granted under and governed by the terms and conditions of the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Option Agreement, both of which are attached and made a part of this document.

** Options will vest in approximately equal annual 25% installments. Full Vest Dates will occur on the first, second, third and fourth anniversaries of the Grant Date.

*** Date to be 10 years from the Grant Date.

REGENERON PHARMACEUTICALS, INC.

Non-Qualified Stock Option

OPTION AGREEMENT
PURSUANT TO
THE AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date of the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Stock Options* (the "Grantee"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Grantee is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee (or the person or persons to whom the Committee has delegated the relevant authority pursuant to Section 4 of the Plan (as defined below) (the Committee or such person or persons being referred to in this Agreement as the "Committee")) administering the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the option (the "Option") to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option becomes exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Sections 7(c)(1) (if applicable) and 7(c)(2) of the Plan, the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having an aggregate Fair Market Value (as measured on the date of exercise) equal to the aggregate Option exercise price due upon such exercise. The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall become entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that (except with respect to retirement on the terms set forth below) the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (the Company and all Subsidiaries shall be referred to herein, collectively, as the "Employer," and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on such Full Vest Dates. Except as otherwise provided below or in the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by or provide services to the Employer and the entire unvested portion of the Option shall be forfeited at such time. Notwithstanding the preceding sentence, upon the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof), the Option shall continue to vest in installments as provided in the *Notice of Grant of Stock Options* as if the Grantee had continued to be employed by or provide services to the Employer. For the avoidance of doubt and notwithstanding anything herein or in the *Notice of Grant of Stock Options* to the contrary, any outstanding and unvested portion of the Option shall become fully vested on the date of the Grantee's death. The provisions of this Section 2(b) are subject to (i) the provisions set forth in the

Notice of Grant of Stock Options or any employment agreement, consulting agreement or similar agreement in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* and (ii) the Committee's determination in accordance with Section 7(e) of the Plan.

(c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of a Change in Control. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Section 4999 of the Code (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Grantee; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as may be determined by the Committee in accordance with Section 7(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement (as defined in the Company's employee handbook as in effect on the date hereof), or long-term disability; (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement (as defined in the Company's employee handbook as in effect on the date hereof) or the Grantee's death; (C) one year after the termination if such termination is due to the Grantee's long-term disability; (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered); or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is not due to death, retirement, or long-term disability.

(b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Company and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer (other than any such failure resulting from his or her incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Employer, violation of the Employer's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours; (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Grantee (or otherwise applicable to the Grantee) on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in

its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Shareholder. The Grantee shall have no rights as a shareholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates or book-entry registration or registrations for such shares. Except as provided in Section 3(c) of the Plan, no adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

6. Compliance with Law and Regulations. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates or register book entries evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates or the registration of such book entries is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates and book entries bear or be subject to such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

10. Recoupment. By entering into this Agreement and accepting the award hereunder, the Grantee agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Option and any shares of Common Stock issued pursuant thereto.

Notice of Grant of Award and Restricted Stock Agreement

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[NAME]
[ADDRESS]

RSA Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted an award of [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") common stock. These shares are restricted until the vest date(s) shown below.

The current total value of the award is $[ ].

The award will vest in full on the date(s) shown.

Shares	Full Vest Date
[ ]*	[ ]*

You and the Company agree that this award is granted under and governed by the terms and conditions of the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Restricted Stock Agreement, both of which are attached and made a part of this document.

* Awards designated as annual awards will vest 50% on the second anniversary of the Grant Date and 50% on the fourth anniversary of the Grant Date. Awards designated as special awards will vest in their entirety on the fourth anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK AGREEMENT
PURSUANT TO
THE AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Restricted Stock*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Restricted Stock* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock*) to the Recipient the shares of Restricted Stock as set forth in the *Notice of Grant of Restricted Stock*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 8 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the number of shares of Restricted Stock as shown on the *Notice of Grant of Restricted Stock*. The Participant's grant and record of Restricted Stock share ownership shall be kept on the books of the Company until the restrictions on transfer have lapsed. At the Recipient's request, vested shares may be evidenced by stock certificates or book-entry registration.

2. **Vesting**. (a) The shares of Restricted Stock granted to the Recipient shall vest in installments as provided in the *Notice of Grant of Restricted Stock*. The vesting schedule in the *Notice of Grant of Restricted Stock* indicates each date upon which the restrictions on transfer on the specified number of shares of Restricted Stock shall lapse, entitling the Recipient to freely transfer such shares, provided that the Recipient has not [(except with respect to retirement on the terms set forth below)][1] incurred a termination of employment with the Company and all Subsidiaries (the Company and its Subsidiaries shall be referred to herein, collectively, as the "Employer"). There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Restricted Stock* and all vesting shall occur only on such Full Vest Dates. No vesting shall occur after the termination of the Recipient's employment with the Employer for any reason [(except with respect to retirement on the terms set forth below)][2]. The provisions of this Section 2(a) are subject to (i) the provisions set forth in the *Notice of Grant of Restricted Stock* or any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock* and (ii) the Committee's determination in accordance with Section 8(h) of the Plan.

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[1]Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.
[2]Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.

(b) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Restricted Stock* to the contrary, but subject to the provisions of any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock*, the Restricted Stock granted to Recipient shall be fully vested on the date the Recipient's employment with the Employer is terminated if the Recipient's employment with the Employer is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Recipient for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Recipient upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

(c) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Recipient substantially to perform his or her duties and obligations to the Employer (other than any such failure resulting from his or her incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Employer, violation of the Employer's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of the duties of the Recipient's employment with the Employer, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours; (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified on the *Notice of Grant of Restricted Stock* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 2(c), no act, or failure to act, on the Recipient's part shall be considered "willful" unless done, or omitted to be done, by the Recipient in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

(d) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Recipient within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Recipient to the Employer that Recipient intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Recipient's duties and responsibilities from those which existed

immediately prior to a Change in Control (except in each case in connection with the termination of the Recipient's employment for Cause or as a result of the Recipient's death, or temporarily as a result of the Recipient's illness or other absence), or (2) the assignment to the Recipient of duties and responsibilities materially inconsistent with the position held by the Recipient; (B) any material breach by the Employer of any material provision of any written agreement with the Recipient or failure to timely pay any compensation obligation to the Recipient; (C) a reduction in the Recipient's annual base salary or target bonus opportunity (if any) from that which existed immediately prior to a Change in Control; or (D) if the Recipient is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Recipient's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date on the *Notice of Grant of Restricted Stock* that defines "good reason" (or words of like import), as defined under such agreement or plan[; provided, however, that any such definition shall be deemed, solely for purposes of this Agreement, to include as one of the reasons that the employment of Leonard S. Schleifer, M.D. Ph.D. with the Company under the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between Dr. Schleifer and the Company, as in effect from time to time (the "Employment Agreement"), has ended due to Dr. Schleifer's Involuntary Termination (as defined in the Employment Agreement)][3].

3. **Termination of Service**. Subject to the terms of the Plan and Section 2(b) hereof, if the Recipient's employment with the Company is terminated for any reason (other than as set forth in Section 2(b) hereof and as a result of Recipient's [retirement on the terms set forth below or][4] death), the Recipient shall forfeit any or all of the shares of Restricted Stock that have not vested in accordance with Section 2 hereof (the "Unvested Shares"). [Notwithstanding the preceding sentence, upon the Recipient's retirement (as defined in the Company's employee handbook as in effect on the date hereof), shares of Restricted Stock granted to the Recipient shall continue to vest in installments as provided in the *Notice of Grant of Restricted Stock* as if the Recipient had continued to be employed by or provide services to the Employer.][5] Shares of Restricted Stock granted to the Recipient in the Notice of Grant of Restricted Stock shall become fully vested as of the date of death of the Recipient, provided that the Recipient is employed by the Employer on the date of his/her death.

4. **Restrictions on Transfer**. Unvested Shares may not be transferred or otherwise disposed of by the Recipient including by way of sale, assignment, transfer, pledge, hypothecation or otherwise, except as permitted by the Committee in its sole discretion.

5. **Securities Laws Requirements**. The Company shall not be obligated to transfer any Unvested Shares or other shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

6. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the shares of Restricted Stock by any holder thereof in violation of the provisions of this Agreement or the Certificate of Incorporation or the By-Laws of the Company, shall be valid, and the Company will not transfer any of said shares of Restricted Stock on its books nor will any of said shares of Restricted Stock be entitled to vote, nor will any dividends be paid thereon, unless and until there has been full compliance with said provisions to the satisfaction of the Company. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

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[3]Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.
[4]Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.
[5]Only applicable to Restricted Stock Agreements for George D. Yancopoulos, M.D., Ph.D.

7. **Taxes**. The Recipient shall promptly notify the Company of any election made pursuant to Section 83(b) of the Code. The Recipient shall pay to the Company, at the time the Recipient recognizes taxable income in respect to the shares of Restricted Stock as a result of having made an election under Section 83(b) of the Code in connection with such grant, an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the shares of Restricted Stock. The Recipient may satisfy the foregoing requirement by making a payment to the Company in cash or, with the consent of the Company, by authorizing the Company to withhold cash otherwise due to the Recipient. In all other cases (except as may be otherwise determined by the Board of Directors or the Committee from time to time (including following the date hereof)), any such withholding obligation shall be satisfied by surrendering to the Company a portion of the shares of Restricted Stock the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of such shares on the date of such vesting (and the amount equal to the Fair Market Value of such shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that he or she (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Agreement.

THE RECIPIENT ACKNOWLEDGES THAT IT IS THE RECIPIENT'S SOLE RESPONSIBILITY, AND NOT THE COMPANY'S, TO FILE TIMELY THE ELECTION UNDER SECTION 83(b) OF THE CODE, IN THE EVENT THAT THE RECIPIENT DESIRES TO MAKE THE ELECTION.

8. **Rights as a Shareholder**. Pursuant to Section 8(e) of the Plan, the Company shall hold in escrow all dividends, if any, that are paid with respect to the Unvested Shares until all restrictions on such shares have lapsed. Pursuant to Section 8(f) of the Plan, the Recipient agrees (i) that the right to vote any Unvested Shares will be held by the Company and (ii) to execute an irrevocable proxy in favor of the Company in such form supplied by the Company.

9. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing Restricted Stock pursuant to the terms hereof, that the certificates or book entries bear or be subject to such legends as set forth in the Plan, in addition to any other legends required under federal and state securities laws or as otherwise determined by the Committee. Except to the extent preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

10. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

11. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 11.

12. **No Obligation to Continue Employment**. This Agreement does not guarantee that the Employer will employ the Recipient for any specified time period, nor does it modify in any respect the Recipient's employment or compensation.

13. **Recoupment**. By entering into this Agreement and accepting the award hereunder, the Recipient agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the shares of Restricted Stock granted hereunder (including after all restrictions on such shares have lapsed).

Notice of Grant of Stock Options and Option Agreement

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[OPTIONEE NAME]
[OPTIONEE ADDRESS]

Option Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted a Non-Qualified Option to buy [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock at $[ ] per share.

The total option price of the shares granted is $[ ].

Full Vest Dates: This option will vest and become exercisable (i) on the date of the Company's [ ]* Annual Meeting of Shareholders with respect to a pro-rata portion of the total number of shares underlying the option equal to the portion of one year that has elapsed from the date of grant to the date of the Company's [ ]* Annual Meeting of Shareholders, and (ii) on [/ /]** with respect to the remainder of the shares underlying the option. Assuming the [ ]* Annual Meeting of Shareholders occurs on [/ /] as currently planned, this option will vest and become exercisable with respect to [ ] underlying shares on [/ /] and with respect to [ ] underlying shares on [/ /]**.

You and the Company agree that these options are granted under and governed by the terms and conditions of the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Option Agreement, both of which are attached and made a part of this document.

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* The next Annual Meeting of Shareholders following the Grant Date.

** First anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

Non-Qualified Stock Option

OPTION AGREEMENT
PURSUANT TO
THE AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN
(Non-Employee Director Grant)

THIS AGREEMENT (this "Agreement"), made as of the date of the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the individual named on the *Notice of Grant of Stock Options* (the "Grantee"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Grantee is a non-employee member of the board of directors of the Company (the "Board") and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. Grant of Award. Pursuant to Section 12 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the option (the "Option") to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Vesting; Exercise. (a) The Option becomes exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7(c)(2) of the Plan, the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having an aggregate Fair Market Value (as measured on the date of exercise) equal to the aggregate Option exercise price due upon such exercise. The Grantee acknowledges that it is the Grantee's responsibility to satisfy any federal, state and local tax requirements related to the exercise of the Option.

(b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall become entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that (except as set forth below with respect to Retirement or the Grantee's death) the Grantee has not incurred a termination of service as a member of the Board prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on such Full Vest Dates. Except as otherwise provided below or in the *Notice of Grant of Stock Options* or as may be otherwise determined by the Committee in accordance with Section 12(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be on the Board and the entire unvested portion of the Option shall be forfeited at such time. Notwithstanding the preceding sentence, upon the Grantee's Retirement from service on the Board, the Option shall continue to vest in installments as provided on the *Notice of Grant of Stock Options* as if the Grantee had remained in service on the Board. For purposes of this Agreement, "Retirement" shall mean a voluntary termination of service on the Board (including by not standing for re-election) by the Grantee at a time when the Grantee meets both of the following criteria: the Grantee has served as a member of the Board for a minimum of three (3) years, and the combination of the Grantee's age and total years of service as a member of the Board equals a minimum of 80.

(c) Notwithstanding anything herein or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of the Grantee's death if the Grantee's service on the Board has not terminated prior to the Grantee's

death. In addition, and also notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of a Change in Control if the Grantee's service on the Board has not terminated prior to such date. If the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee in connection with a Change in Control (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Section 4999 of the Code (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Company and the Grantee or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Grantee; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. Option Term. Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of service as a member of the Board of the Company, except as may be otherwise determined by the Committee in accordance with Section 12(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (D) below, three months after such termination if such termination is for any reason other than death, Retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to Retirement or death, (C) one year after the termination if such termination is due to the Grantee's long-term disability or (D) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is not due to death, Retirement, or long-term disability.

4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.

5. Rights of a Shareholder. The Grantee shall have no rights as a shareholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates or bookentry registration or registrations for such shares. Except as provided in Section 3(c) of the Plan, no adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

6. Compliance with Law and Regulations. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates or register book entries evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates or the registration of such book entries is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates or the registration of book entries evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates and book entries bear or be subject to such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated service, to the last address for the Grantee indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

Notice of Grant of Restricted Stock Units and Restricted Stock Agreement

Regeneron Pharmaceuticals, Inc.
ID: [ ]
777 Old Saw Mill River Road
Tarrytown, New York 10591

[NAME]
[ADDRESS]

RSU Number: **[ ]**
Plan: **[ ]**
ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted restricted stock units with respect to [ ] shares of Regeneron Pharmaceuticals, Inc. (the "Company") stock.

The total current value of the award is $[ ].

Full Vest Dates: These restricted stock units will vest (i) on the date of the Company's [ ]* Annual Meeting of Shareholders with respect to a pro-rata portion of the total number of shares underlying the award equal to the portion of one year that has elapsed from the date of grant to the date of the Company's [ ]* Annual Meeting of Shareholders, and (ii) on [/ /]** with respect to the remainder of the shares underlying the award. Assuming the [ ]* Annual Meeting of Shareholders occurs on [/ /] as currently planned, these restricted stock units will vest respect to [ ] underlying shares on [/ /] and with respect to [ ] underlying shares on [/ /]**. Vested restricted stock units remain subject to the tax deferral provisions set forth in the enclosed Restricted Stock Unit Agreement.

You and the Company agree that these restricted stock units are granted under and governed by the terms and conditions of the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long Term Incentive Plan, as amended from time to time, and the enclosed Restricted Stock Unit Agreement, both of which are attached and made a part of this document.

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* The next Annual Meeting of Shareholders following the Grant Date.

** First anniversary of the Grant Date.

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK UNIT AGREEMENT
PURSUANT TO
THE AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Restricted Stock Units*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the individual named on the *Notice of Grant of Restricted Stock Units* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is a non-employee member of the board of directors of the Company (the "Board") and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock Units*) to the Recipient a Restricted Stock Unit (as defined below) with respect to the number of shares of Company Stock as set forth in the *Notice of Grant of Restricted Stock Units*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 9 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, a restricted stock unit (referred to in the Plan as "Phantom Stock") (each such unit, a "Restricted Stock Unit") with respect to the number of shares of Company Stock as shown on the Notice of Grant of Restricted Stock Units. The Recipient's record of Company Stock ownership shall be recorded in the books of the Company only when the Restricted Stock Units vest and the shares of Company Stock are issued. At the Recipient's request, vested shares may be evidenced by stock certificates or book-entry registration.

2. **Vesting; Delivery**. (a) The Restricted Stock Units granted to the Recipient shall vest in installments as provided in the Notice of Grant of Restricted Stock Units. The vesting schedule in the Notice of Grant of Restricted Stock Units indicates each date upon which the Restricted Stock Units shall vest, entitling the Recipient to receive the underlying shares of Company Stock, provided that the Recipient has not incurred a termination of service as a member of the Board. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the Notice of Grant of Restricted Stock Units and all vesting shall occur only on such Full Vest Dates. No vesting shall occur after the termination of the Recipient's service as a member of the Board for any reason. Notwithstanding the preceding sentence, upon the Recipient's Retirement from service on the Board, the Restricted Stock Units shall continue to vest in installments as provided on the Notice of Grant of Restricted Stock Units as if the Recipient had remained in service on the Board. For purposes of this Agreement, "Retirement" shall mean a voluntary termination of service on the Board (including by not standing for re-election) by the Recipient at a time when the Recipient meets both of the following criteria: the Recipient has served as a member of the Board for a minimum of three (3) years, and the combination of the Recipient's age and total years of service as a member of the Board equals a minimum of 80.

(b) Notwithstanding anything herein (except the following sentence) or in the Notice of Grant of Restricted Stock Units to the contrary, outstanding Restricted Stock Units granted to Recipient shall be fully vested on the date of a Change in Control or upon the Recipient's death. If the application of the provision in the foregoing sentence, similar provisions in other stock option or equity compensation grants, and other payments and benefits payable to the Recipient (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local

income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Company and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

(c) Unless a later delivery date is elected by the Recipient at a time and in a manner which complies with the requirements of Section 409A of the Code (and the regulations thereunder), shares of Company Stock issuable pursuant to the vesting of Restricted Stock Units shall be delivered on the earlier of (1) the termination of the Recipient's service as a member of the Board, (2) the seventh anniversary of the date of grant of the Restricted Stock Units and (3) the date of a Change in Control (provided that the shares of Company Stock may be delivered upon such Change in Control without violating Section 409A of the Code). With respect to Restricted Stock Units which become vested following termination of the Recipient's service as a member of the Board pursuant to the last two sentences of Section 2(a), shares of Company Stock with respect thereto shall be delivered as soon as practicable following vesting, unless a later delivery date is elected by the Recipient at a time and in a manner which complies with the requirements of Section 409A of the Code (and the regulations thereunder).

3. **Termination of Service**. Subject to the terms of the Plan and Section 2 hereof, if the Recipient's service on the Board is terminated for any reason (other than as set forth in Section 2 hereof), the Recipient shall forfeit any or all of the shares of Company Stock subject to the Restricted Stock Unit that have not vested in accordance with Section 2 hereof.

4. **Securities Laws Requirements**. The Company shall not be obligated to transfer any shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

5. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the Restricted Stock Units by any holder thereof in violation of the provisions of this Agreement or the Certificate of Incorporation or the By-Laws of the Company shall be valid. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

6. **Rights as a Shareholder**. The Recipient will not have the rights of a shareholder with respect to shares of Company Stock subject to the Restricted Stock Units until the vesting of the Restricted Stock Units and the delivery of shares of Company Stock with respect to such vesting. To the extent that the Company declares a cash dividend while all or a portion of the Restricted Stock Units are unvested, the Recipient shall be credited with dividend equivalent rights with respect to each share of Company Stock subject to the unvested portion of the Restricted Stock Units. Such dividend equivalent right will entitle the Recipient to payment of such dividend only upon vesting of the corresponding portion of the Restricted Stock Unit; and such right will be forfeited to the extent the corresponding portion of the Restricted Stock Unit is forfeited.

7. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. Except to the extent preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

8. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

9. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company,

to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 9.

Regeneron Pharmaceuticals, Inc.

ID: [ ]

777 Old Saw Mill River Road

Tarrytown, New York 10591

Notice of Grant of Performance Restricted Stock Units and Performance Restricted Stock Unit Agreement ("Notice")

[NAME]

[ADDRESS]

Performance RSU Number: **[ ]**

Plan: **[ ]**

ID: **[ ]**

Effective <date> (the "Grant Date") you have been granted Performance Restricted Stock Units with respect to a target number of [ ] shares of REGENERON PHARMACUTICALS, INC. (the "Company") common stock (the "Target PSU"). Please refer to Section 2, Definitions below for definitions of certain terms used in this Notice. Any capitalized term used but not defined in this Notice shall have the meaning given to such term in the Plan.

1. Vesting Criteria and Rules.

A. Primary Performance Schedule.

The Performance Restricted Stock Units shall be eligible to vest based on determinations that are to be made first upon the fourth anniversary of the Grant Date and second upon the fifth anniversary of the Grant Date, subject to earlier determinations upon a Change in Control. Rules regarding the timing of issuance of shares of Company Stock in connection with the vesting of Performance Restricted Stock Units are set forth below under Section 3, Special Rules ("Special Rules").

The number of shares of Company Stock deliverable in respect of determinations that are to be made upon the fourth anniversary of the Grant Date shall be based on the following matrix (the "4-Year Goal"):

4-Year Goal

Level	Cumulative TSR	Payout (as percentage of Target PSU)
Maximum	+75%	225%
	+69%	200%
	+63%	175%
	+57%	150%
	+52%	125%
Target	+46%	100%
	+34%	75%
Threshold	+22%	50%

5-Year Goal

The number of shares of Company Stock deliverable in respect of determinations that are to be made upon the fifth anniversary of the Grant Date shall be based on the following matrix (the "5-Year Goal"), except that the number of shares of Company Stock deliverable shall be net of the number (if any) of shares of Company Stock previously delivered in respect of the 4-Year Goal:

Level	Cumulative TSR	Payout (as percentage of Target PSU)
Maximum	+101%	225%
	+93%	200%
	+84%	175%
	+76%	150%
	+69%	125%
Target	+61%	100%
	+44%	75%
Threshold	+28%	50%

No Performance Restricted Stock Units shall vest for performance below the Threshold level (except as set forth below under Section 1.B, Secondary Relative TSR Performance Schedule (the "Secondary Relative TSR Performance Schedule")) and no additional payments shall be made for payments above the Maximum level. There shall be straight line interpolation to determine the payout percentage earned for performance above the Threshold level and falling between the percentages specified in the matrices shown above and below. In the event of a Change in Control prior to the fourth anniversary of the Grant Date, the performance period shall be deemed to have ended on the date of the Change in Control and the payment of Company Stock shall be based on the compound annual growth rate ("CAGR") of the TSR attained as of such date for the shortened performance period (as determined by the Committee) measured against the CAGR levels set forth in the matrix below. In the event of a Change in Control between the fourth and fifth anniversaries of the Grant Date, the performance period shall be deemed to have ended on the date of the Change in Control and the payment of Company Stock shall be based on the CAGR of the TSR attained as of such date for the shortened performance period (as determined by the Committee) measured against the CAGR levels set forth in the matrix below, net of any shares paid pursuant to the determination of the 4-Year Goal. Further, in the event that no Performance Restricted Stock Units have vested hereunder pursuant to the CAGR of the TSR attained for a shortened performance period (whether or not occurring after the first four years of the performance period), the Secondary Relative TSR Performance Schedule shall be applied, except that the relative TSR described therein shall be determined over the shortened performance period.

The following CAGR matrix shall be used to determine the number of shares of Company Stock deliverable in respect of TSR performance over a shortened performance period:

Level	CAGR	Payout (as percentage of Target PSU)
Maximum	+15%	225%
	+14%	200%
	+13%	175%
	+12%	150%
	+11%	125%
Target	+10%	100%
	+7.5%	75%
Threshold	+5%	50%

B. Secondary Relative TSR Performance Schedule

If, immediately following the determination of performance against the 5-Year Goal (or upon a shortened performance period due to a Change in Control, as described above), (1) no Performance Restricted Stock Units have vested hereunder and (2) the Company's TSR for such 5-year period (or shortened performance period, as applicable) is at least 200 basis points above the TSR of the Nasdaq Biotech Index (composite return) as determined by the Committee for the corresponding period, then a number of Performance Restricted Stock Units equal to 50% of the Target PSU shall vest hereunder.

To the extent not earned pursuant to the criteria set forth above, the Performance Restricted Stock Units shall be forfeited upon the fifth anniversary of the Grant Date.

2. Definitions.

"Beginning Stock Price" shall mean the Fair Market Value of a share of the Company Stock on the Grant Date.

"Closing Price" of a share of Company Stock, as of a date of determination, shall mean (1) the closing sales price per share of Company Stock on the national securities exchange or national market system on which such stock is principally traded on such date or, if such date is not a trading day, on the last preceding date on which there was a sale of such stock on such exchange, or (2) if the shares of Company Stock are not then listed on a national securities exchange or national market system, or the value of such shares is not otherwise determinable, such value as determined by the Committee in good faith.

"Dividend Value" shall mean the value of any dividends paid on a share of Company Stock during the applicable measurement period, with the payment date deemed to have occurred on the ex-dividend date for such dividend and the amount of such dividend deemed reinvested in shares of Company Stock as of the ex-dividend date (based on the Closing Price of such shares on such date).

"Ending Stock Price" shall mean the average Closing Price of a share of Company Stock for the twenty trading days immediately preceding the applicable determination date, after adjusting for the Dividend Value, as applicable.

"Plan" shall mean the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan, as amended from time to time.

"TSR" shall mean the percent return on a share of Company Stock, determined using the following calculation:

TSR = (Ending Stock Price - Beginning Stock Price)/(Beginning Stock Price)

3. Special Rules.

Upon a termination of employment due to death or retirement (as defined in the Company's employee handbook as in effect on the date hereof) (such retirement, "Retirement"), the Performance Restricted Stock Unit award shall remain outstanding, and vesting and forfeiture shall be determined in the manner set forth in this Notice, without regard to such termination of employment.

For the avoidance of doubt, and notwithstanding any provision in this Notice, the Performance Restricted Stock Unit Agreement, or the Plan to the contrary, no termination of employment shall be deemed to take place unless the Recipient has ceased both to be employed by and to provide service [(other than continued service on the board of directors of the successor, surviving, or resulting entity of the Company following a Change in Control, as described below)][1] to the Company and/or its Subsidiaries.

[1] Not applicable to Notices for P. Roy Vagelos, M.D.

Upon any termination of employment other than (1) due to death, (2) due to Retirement, or (3) following a Change in Control, any unvested portion of the Performance Restricted Stock Units shall be immediately forfeited.

In the event that the Company pays dividends during a performance period, the number of shares of Company Stock subject to the Target PSU shall be increased by a number of shares of Company Stock equal to the aggregate amount of the dividend payable with respect to the number of shares of Company Stock subject to the Target PSU, divided by the Fair Market Value of a share of the Company Stock on the ex-dividend date with respect to such dividend.

[Except in the case of vesting determinations made early due to the occurrence of a Change in Control, shares][2] [Shares][3] of Company Stock earned pursuant to the Performance Restricted Stock Unit Agreement and this Notice shall be delivered (subject to satisfaction of the applicable tax withholding requirements) as soon as practicable (but in no event more than 30 days) following the applicable vesting determination described above, which shall be made by the Committee within 30 days following completion of the applicable performance period.

[In the case of vesting determinations made early due to the occurrence of a Change in Control, shares of Company Stock earned pursuant to the Performance Restricted Stock Unit Agreement and this Notice based on a determination made as a result of such Change in Control shall be delivered (subject to satisfaction of the applicable tax withholding requirements) as soon as practicable (but in no event more than 30 days) following the fifth anniversary of the Grant Date (subject to your continued employment upon such anniversary); provided, however, that in the event that your employment is terminated prior to such fifth anniversary and upon or within the two-year period immediately following the Change in Control either by the Company without Cause (as defined below) or by you for Good Reason (as defined below) or due to your death, such shares shall be delivered upon or within 30 days following such termination (and shall be forfeited upon any other termination of employment). In addition, in the event that the Performance Restricted Stock Units are not assumed or converted into an economically-equivalent right upon a Change in Control, Performance Restricted Stock Units earned as a result of vesting determinations made early due to the occurrence of a Change in Control shall be delivered upon or as soon as practicable following the Change in Control.

For purposes of this Notice, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by you substantially to perform your duties and obligations to the Company (other than any such failure resulting from your incapacity due to physical or mental illness), including without limitation, repeated refusal to follow the reasonable directions of the Company, violation of the Company's Code of Business Conduct and Ethics, knowing violation of law in the course of performance of your duties of employment, repeated absences from work without a reasonable excuse, or intoxication with alcohol or illegal drugs while on the Company's premises during regular business hours; (B) fraud or material dishonesty against the Company; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this paragraph, no act, or failure to act, on your part shall be considered "willful" unless done, or omitted to be done, by you in bad faith and without reasonable belief that the action or omission was in the best interest of the Company.

For purposes of this Notice, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by you within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control

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[2] Not applicable to Notices for P. Roy Vagelos, M.D.

[3] Only applicable to Notices for P. Roy Vagelos, M.D.

unless such events are fully corrected in all material respects by you within thirty (30) days following written notification by you to the Company that you intend to terminate your employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in your duties and responsibilities from those which existed immediately prior to a Change in Control (except in each case in connection with the termination of your employment for Cause or as a result of your death, or temporarily as a result of your illness or other absence), or (2) the assignment to you of duties and
responsibilities materially inconsistent with the position held by you; (B) any material breach by the Company of any material provision of any written agreement with you or failure to timely pay any compensation obligation to you; (C) a reduction in your annual base salary or target bonus opportunity (if any) from that which existed immediately prior to a Change in Control; or (D) if you are based at the Company's principal executive office, any relocation therefrom or, in any event, a relocation of your primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between you and the Company (or otherwise applicable to you) on the Grant Date that defines "good reason" (or words of like import), as defined under such agreement or plan[; provided, however, that any such definition shall be deemed, solely for purposes of this Notice, to include as one of the reasons that the employment of Leonard S. Schleifer, M.D., Ph.D. with the Company under the Amended and Restated Employment Agreement, dated as of November 14, 2008, by and between Dr. Schleifer and the Company, as in effect from time to time (the "Employment Agreement"), has ended due to Dr. Schleifer's Involuntary Termination (as defined in the Employment Agreement)].[4]][5] [For purposes of this Notice, in the event of a termination without Cause or for Good Reason on or within the two-year period following a Change in Control, continued service on the board of directors of the successor, surviving, or resulting entity of the Company in a Change in Control transaction shall not affect the payment timing (which shall be upon or within 30 days following such termination).[6]]

You and the Company agree that these Performance Restricted Stock Units are granted under and governed by the terms and conditions of the Plan and the enclosed Performance Restricted Stock Unit Agreement, both of which are attached and made a part of this document. You and the Company further agree that these Performance Restricted Stock Units are intended to be short-term deferrals exempt from the provisions of Section 409A of the Code and shall be construed and interpreted in accordance with such intention.

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[4] Only applicable to Notices for George D. Yancopoulos, M.D., Ph.D.
[5] Not applicable to Notices for P. Roy Vagelos, M.D.
[6] Not applicable to Notices for P. Roy Vagelos, M.D.

REGENERON PHARMACEUTICALS, INC.

PERFORMANCE RESTRICTED STOCK UNIT AGREEMENT
PURSUANT TO
THE AMENDED AND RESTATED REGENERON PHARMACEUTICALS, INC.
2014 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT (this "Agreement"), made as of the date on the *Notice of Grant of Performance Restricted Stock Units*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company" and, together with its Subsidiaries, the "Employer"), and the employee named on the *Notice of Grant of Performance Restricted Stock Units* (the "Recipient"). Any capitalized term used but not defined in this Agreement shall have the meaning given to such term in the Plan (as defined below).

WHEREAS, the Recipient is an employee of the Company (or a Subsidiary of the Company) and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Performance Restricted Stock Units*) to the Recipient a Performance Restricted Stock Unit (as defined below) with respect to the number of shares of Company Stock as set forth in the *Notice of Grant of Performance Restricted Stock Units*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

1. **Grant of Award**. Pursuant to Section 9 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, a restricted stock unit (referred to in the Plan as "Phantom Stock") (each such unit, a "Performance Restricted Stock Unit") with respect to the shares of Company Stock as determined in accordance with the *Notice of Grant of Performance Restricted Stock Units*. The Participant's record of Company Stock ownership shall be recorded in the books of the Company only when and to the extent the Performance Restricted Stock Units vest and the shares of Company Stock are issued. At the Recipient's request, vested shares may be evidenced by stock certificates or book-entry registration.

2. **Vesting; Forfeiture**. (a) The Performance Restricted Stock Units granted to the Recipient shall vest and be forfeited as provided in the *Notice of Grant of Performance Restricted Stock Units*. The provisions of this Section 2(a) are subject to the provisions set forth in the *Notice of Grant of Performance Restricted Stock Units* and any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Performance Restricted Stock Units*.

(b) Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or plan, or similar agreement or plan in effect between the Employer and the Recipient (or otherwise applicable to the Recipient) on the date of grant specified in the *Notice of Grant of Performance Restricted Stock Units*, if the application of the Change in Control provisions set forth in the *Notice of Grant of Performance Restricted Stock Units*, similar provisions in other stock option or equity compensation grants, and other payments and benefits payable to the Recipient upon termination of employment with the Employer (collectively, the "Company Payments") would result in the Recipient being subject to excise tax (the "Excise Tax") payable under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order: (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur; (2) any lump-sum severance based on a multiple of base salary or bonus; (3) any other cash amounts payable to the Recipient; (4) any benefits valued as parachute payments; and (5) acceleration of vesting of any equity not covered by (1) above.

3. **Reserved.**

4. **Securities Laws Requirements**. The Company shall not be obligated to transfer any shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).

5. **Invalid Transfers**. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the Performance Restricted Stock Units by any holder thereof in violation of the provisions of this Agreement or the Certificate of Incorporation or the By-Laws of the Company shall be valid. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.

6. **Taxes**. At the time the Recipient recognizes taxable income in respect of the Performance Restricted Stock Units, an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the Performance Restricted Stock Units shall be due from the Recipient to the Company and shall (except as may otherwise be determined by the Board of Directors or the Committee from time to time (including following the date hereof)) be satisfied by surrendering to the Company a portion of the shares of Company Stock otherwise deliverable with respect to the Performance Restricted Stock Units the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of such shares on the date of such vesting (and the amount equal to the Fair Market Value of such shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that he or she (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Agreement.

7. **Rights as a Shareholder**. The Recipient will not have the rights of a shareholder with respect to shares of Company Stock subject to the Performance Restricted Stock Units until the vesting of the Performance Restricted Stock Units and the delivery of shares of Company Stock with respect to such vesting.

8. **Compliance with Law and Regulations**. This Agreement, the award hereunder and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. Except to the extent preempted by any federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

9. **Recipient Bound by Plan**. The Recipient acknowledges receipt of a copy of this Agreement and the Plan and agrees to be bound by all the terms and provisions thereof, which are incorporated herein by reference. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.

10. **Notices**. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 10.

11. **No Obligation to Continue Employment**. This Agreement does not guarantee that the Employer will employ the Recipient for any specified time period, nor does it modify in any respect the Recipient's employment or compensation.

12. **Recoupment**. By entering into this Agreement and accepting the award hereunder, the Recipient agrees to be bound by the terms of the Company's Policy Regarding Recoupment or Reduction of Incentive Compensation for Compliance Violations, as in effect from time to time (or any successor policy thereto) (the "Recoupment Policy"), and further acknowledges and agrees that the Recoupment Policy shall apply to the Performance Restricted Stock Units and the shares of Company Stock deliverable pursuant to the Performance Restricted Stock Units granted hereunder (including after all restrictions on such shares have lapsed).

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

SECOND AMENDMENT AGREEMENT

This Second Amendment Agreement ("Second Amendment Agreement") is made and effective as of December 19th, 2019 (the "Effective Date") with the Parties' obligations hereunder to commence on January 1st, 2022 (the "Commencement Date") by and between (i) Regeneron Ireland Designated Activity Company ("RIRE") and (ii) Bayer Healthcare LLC ("Bayer").

WHEREAS, Regeneron Pharmaceuticals, Inc., the ultimate parent company of RIRE, ("Regeneron") and Bayer were Parties to a License and Collaboration Agreement having an effective date of October 18, 2006, which was amended by a Restated Amendment Agreement effective May 7, 2012 and dated December 30, 2014 ("Restated Amendment Agreement") to reflect changes in the financial and other arrangements with respect to the Commercialization of Licensed Products in Japan (the said License and Collaboration Agreement, as amended, the "LCA") and partially assigned to RIRE;

WHEREAS, Regeneron and Bayer agreed that Licensed Products would be Commercialized in Japan by Santen Pharmaceutical Co., Ltd. ("Santen") pursuant to a Co-Promotion and Distribution Agreement by and between Bayer Yakuhin, Ltd ("BYL") and Santen dated May 7, 2012 which was subsequently amended on July 14th, 2016 (the said Co-Promotion and Distribution Agreement, as amended, the "Santen Co-Promotion Agreement");

WHEREAS, the Santen Co-Promotion Agreement will expire on December 31st, 2021 and BYL and Santen would like to extend it, subject to the terms and conditions of an Amended and Restated Co-Promotion and Distribution Agreement (the "Extended Santen Co-Promotion Agreement");

WHEREAS, the Parties would like to revise several terms and conditions in the Santen Co-Promotion Agreement considering the anticipated changes to the Anti-VEGF market in the future and a potential launch of a Licensed Product bio-identical; and

WHEREAS, the extension and changes to the Santen Co-Promotion Agreement require the consent of RIRE and certain further amendments to the LCA.

NOW THEREFORE, in consideration of the promises set forth herein, and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Definitions**. Capitalized terms used in this Second Amendment Agreement which are not defined herein and are defined in the LCA shall have the meanings ascribed to them in the LCA. Capitalized terms used in this Second Amendment Agreement which are not defined herein and are not defined in the LCA shall have the meanings ascribed to them in the Santen Co-Promotion Agreement or the Extended Santen Co-Promotion Agreement and such definitions are hereby deemed incorporated by reference into Article I of the LCA.

2. **Date of Commencement**. The Santen Co-Promotion Agreement shall continue in force until December 31, 2021 and the Extended Santen Co-Promotion Agreement shall become effective on the Commencement

Date. The Restated Amendment Agreement shall also continue to apply until December 31, 2021 with this Second Amendment Agreement becoming effective on the Commencement Date.

3. **Continuing Effect**. Except as specifically modified by this Second Amendment, all of the provisions of the LCA (including the Restated Amendment Agreement) are hereby ratified and confirmed to be in full force and effect. Where references are made in the Restated Amendment Agreement to the Santen Co-Promotion Agreement, following the Commencement Date such references shall be to the Extended Santen Co-Promotion Agreement.

4. **Regeneron Consent to Sublicense Grant**. RIRE hereby expressly agrees and consents for the Initial Extension Term and for the Renewal Term (as defined in the Extended Santen Co-Promotion Agreement) to a sublicense by Bayer to BYL of Bayer's rights under the Regeneron Intellectual Property granted by RIRE to Bayer pursuant to the LCA provided such sublicense is in compliance with Section 4.3 of the LCA unless agreed in writing by RIRE with Bayer, and to BYL's further sublicense of such rights to Santen, pursuant to the terms of the Extended Santen Co-Promotion Agreement, provided that such agreement and consent shall not alter or affect in any manner Bayer's obligations of RIRE's rights under the LCA which shall remain in full force and effect, including without limitation under such Section 4.3.

5. [***].

6. **Japan Profit Share**. With effect from the Commencement Date, the Purchase Price Adjustment arrangement shall cease to apply, and the Parties shall revert to a profit share arrangement for Japan. In determining the Territory Profit Split in accordance with Schedule 2 of the LCA, the following clarifications and modifications shall apply to Japan:

(a) Net Sales will be calculated on the basis of sales by BYL to Santen with the gross amount invoiced corresponding to [***] pursuant to the Santen Co-Promotion Agreement; and

(b) [***], calculated in accordance with the Extended Co-Promotion Agreement, shall be added as a deduction in Section 1.65 of the LCA in the calculation of Net Sales. [***].

[***].

7. **Treatment of Santen Eylea Inventory on Commencement Date**. As part of the first Global True-Up following the Commencement Date, Bayer will compensate RIRE for the Eylea inventory that Santen has on-hand as of [***]. Such compensation will be calculated according to the following formula: Santen inventory units of Licensed Product in its possession on [***], converted to US Dollars using the Quarter exchange rates.

8. **Schedule 2**. Schedule 2 of the LCA is deleted and replaced with the Amended and Restated Schedule 2 attached to this Second Amendment Agreement, and all references to Schedule 2 in this Second Amendment Agreement or in the LCA from and after the Commencement Date shall refer to such Amended and Restated Schedule 2.

9. **Entire Agreement**. The LCA (including the Restated Amendment Agreement), this Second Amendment Agreement and any written agreements executed by both Parties pertaining to the subject matter therein or herein, contain the complete understanding and entire agreement of the Parties hereto with respect to subject matter hereof and thereof and said documents supersedes all prior understandings and agreements, whether written or oral, relating to the subject matter hereof and thereof. This Second Amendment Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

10. **Headings**. Headings in this Second Amendment Agreement are for convenience of reference only and shall not be considered in construing this Second Amendment Agreement.

11. **Counterparts**. This Second Amendment Agreement may be executed in counterparts, with each part being deemed an original, and that an electronic copy signature shall have the same force and effect as an original signature.

12. **Miscellaneous**. The provisions of Section 20.1 of the LCA shall apply, *mutatis mutandis*, to this Second Amendment Agreement. If there is a direct conflict between the provisions of the LCA (including the Restated Amendment Agreement) and this Second Amendment Agreement, this Second Amendment Agreement shall govern. This Second Amendment Agreement may be amended only by a writing executed by an authorized representative of each of the Parties.

[Signatures appear on following page]

IN WITNESS WHEREOF, each of the Parties has cause this Second Amendment Agreement to be executed as of the date hereof by a duly authorized corporate officer.

REGENERON IRELAND DESIGNATED ACTIVITY COMPANY

By: /s/Muriel O'Byrne
DATE: December 19, 2019

BAYER HEALTHCARE LLC

By: /s/Ganesh Kamath
DATE: December 19, 2019

Amended and Restated Schedule 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the Territory Profit Split for such Quarter (as set forth in Part I), plus (b) the Regeneron Reimbursement Amount for such Quarter (as set forth in Part II), plus or minus (c) the Global True-Up (as set forth in Part III), minus (d) the Global Development Balance Payment (commencing in the Quarter of the First Commercial Sale in a Major Market Country) (as set forth in Part IV). In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Company to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Company in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. TERRITORY PROFIT SPLIT

The "Territory Profit Split" shall mean fifty percent (50%) of Territory Profits in a Quarter. "Territory Profits" shall mean aggregate Net Sales in the Territory in the Quarter less the sum of aggregate COGS and aggregate Shared Promotion Expenses incurred by both Parties in the Territory in the Quarter.

An example of a calculation of the Territory Profit Split in a Quarter would be:

	Aggregate	Company	Regeneron	Territory Profit Split
Net Sales in the Territory	1000	1000		
COGS	(50)	(50)	0	
Shared Promotion Expenses	(350)	(300)	(50)	
Territory Profits	600			300

II. REGENERON REIMBURSEMENT AMOUNT

The "Regeneron Reimbursement Amount" for a Quarter shall mean (a) Shared Promotion Expenses incurred by Regeneron in the Quarter (if any), plus (b) Commercial Supply Costs incurred by Regeneron in the Quarter (if any), plus (c) Development Costs incurred by Regeneron under the Territory Development Plan in the Quarter (if any).

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Promotion Expenses	50
Regeneron Commercial Supply Costs	10
Regeneron Development Costs under Territory Development Plan	5
Regeneron Reimbursement Amount	65

III. GLOBAL TRUE-UP

The "Global True-Up" for a Quarter shall mean (a) fifty percent (50%) of the sum of (i) aggregate Development Costs incurred by both Parties under the Global Development Plan in the Quarter and (ii) aggregate Other Shared Expenses incurred by both Parties in the Quarter, minus (b) one hundred percent (100%) of the sum of (i) Development Costs incurred by Company under the Global Development Plan in the Quarter and (ii) Other Shared Expenses incurred by Company during the Quarter. If the Global True-Up is a positive number, it shall be added in the calculation of the Quarterly True-Up and, if it is a negative number, the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.

An example of a calculation of the Global True-Up in a Quarter would be:

	Aggregate	Company	Regeneron	Global True-Up
Development Costs under Global Development Plan	80	30	50	
Other Shared Expenses	40	35	5	
Total	120	65	55	(5)

IV. GLOBAL DEVELOPMENT BALANCE PAYMENT

The "Global Development Balance" for a Quarter shall mean (a) twenty-five percent (25%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plan from January 1, 2007 through the close of such Quarter ([***]), plus (b) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Territory Development Plan from the Effective Date through the close of such Quarter (excluding Development Overruns in connection with the Territory Development Plan that were not approved by both Parties' representatives on the JSC), less (c) the aggregate amount of Global Development Balance Payments included in the calculation of the Quarterly True-Up in all prior Quarters.

The "Global Development Balance Payment" shall mean [***].

An example of a calculation of the Global Development Balance Payment in a Quarter would be:

Territory Profit Split	300
Global Development Balance	200
[***]	[***]
Global Development Balance Payment	10

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-up in a Quarter would be:

Territory Profit Split	300
Regeneron Reimbursement Amount	200
Global True-Up	(5)
[***]	[***]
Quarterly True-up	[***]

In this example, Company would pay Regeneron [***] in accordance with the terms set forth in Article 9.

SUBSIDIARIES OF REGENERON PHARMACEUTICALS, INC.

Name of Subsidiary*	**State or Other Jurisdiction of Incorporation or Organization**
Loop Road Holdings LLC	New York
Old Saw Mill Holdings LLC	New York
OSMR Holdings	Bermuda
OSMR International	Bermuda
OSMR LLC	New York
Regeneron Assurance, Inc.	New York
Regeneron Atlantic Holdings	Bermuda
Regeneron Belgium BVBA	Belgium
Regeneron Capital International B.V.	The Netherlands
Regeneron Genetics Center LLC	Delaware
Regeneron Healthcare Solutions, Inc.	New York
Regeneron International Holdings LLC	Delaware
Regeneron International Limited	Ireland
Regeneron Ireland Holdings Unlimited Company	Ireland
Regeneron Ireland Designated Activity Company	Ireland
Regeneron Spain, S.L.U.	Spain
Regeneron UK Limited	United Kingdom
Rockwood Road Holdings LLC	New York

* Directly or indirectly wholly owned by Regeneron Pharmaceuticals, Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-228352) and S-8 (Nos. 333-61132, 333-97375, 333-119257, 333-151941, 333-169569, 333-174863, 333-196799, 333-198794, and 333-218669) of Regeneron Pharmaceuticals, Inc., of our report dated February 7, 2020 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 7, 2020

**Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 7, 2020

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert E. Landry, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 7, 2020

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Robert E. Landry, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
February 7, 2020

/s/ Robert E. Landry
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)
February 7, 2020