UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **September 30, 2017**

OR

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(914) 847-7000
(Registrant's telephone number, including area code)

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 X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes X No _____

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

Large accelerated filer	X	Accelerated filer	_____
Non-accelerated filer	_____ (Do not check if a smaller reporting company)	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 Exchange Act).

Yes _____ No X

Number of shares outstanding of each of the registrant's classes of common stock as of October 20, 2017:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,911,456
Common Stock, $.001 par value	105,528,158

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QUARTERLY REPORT ON FORM 10-Q
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 792,065	$ 535,203
Marketable securities	586,879	503,481
Accounts receivable - trade, net	1,532,693	1,343,368
Accounts receivable from Sanofi	217,478	92,989
Accounts receivable from Bayer	221,278	175,263
Inventories	641,588	399,356
Prepaid expenses and other current assets	143,761	130,528
Total current assets	4,135,742	3,180,188
Marketable securities	1,327,303	864,260
Property, plant, and equipment, net	2,274,529	2,083,421
Deferred tax assets	927,023	825,303
Other assets	36,618	20,294
Total assets	$ 8,701,215	$ 6,973,466
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 818,426	$ 879,096
Capital and facility lease obligations	—	129,557
Deferred revenue from Sanofi, current portion	187,036	115,267
Deferred revenue - other, current portion	132,832	116,397
Other current liabilities	334	1,178
Total current liabilities	1,138,628	1,241,495
Capital and facility lease obligations	702,317	351,569
Deferred revenue from Sanofi	408,786	503,474
Deferred revenue - other	274,666	327,298
Other long-term liabilities	125,225	100,385
Total liabilities	2,649,622	2,524,221
Stockholders' equity:		
Preferred Stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,911,456 in 2017 and 2016	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 109,255,150 in 2017 and 107,860,567 in 2016	109	108
Additional paid-in capital	3,570,673	3,029,993
Retained earnings	2,773,214	1,748,222
Accumulated other comprehensive income (loss)	23,835	(12,840)
Treasury Stock, at cost; 3,763,868 shares in 2017 and 2016	(316,240)	(316,240)
Total stockholders' equity	6,051,593	4,449,245
Total liabilities and stockholders' equity	$ 8,701,215	$ 6,973,466

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Statements of Operations				
Revenues:				
Net product sales	$ 957,367	$ 857,468	$ 2,739,745	$ 2,475,869
Sanofi collaboration revenue	245,175	144,392	677,670	527,500
Bayer collaboration revenue	236,625	191,298	640,919	562,786
Other revenue	61,506	26,964	231,446	67,445
	1,500,673	1,220,122	4,289,780	3,633,600
Expenses:				
Research and development	529,749	543,047	1,547,159	1,573,089
Selling, general, and administrative	306,766	270,045	910,520	851,760
Cost of goods sold	46,388	29,901	149,774	150,090
Cost of collaboration and contract manufacturing	57,844	14,327	141,547	74,923
	940,747	857,320	2,749,000	2,649,862
Income from operations	559,926	362,802	1,540,780	983,738
Other income (expense):				
Other income, net	11,861	3,575	2,048	8,937
Interest expense, net	(6,182)	(496)	(19,084)	(4,387)
	5,679	3,079	(17,036)	4,550
Income before income taxes	565,605	365,881	1,523,744	988,288
Income tax expense	(177,288)	(101,077)	(498,752)	(345,881)
Net income	$ 388,317	$ 264,804	$ 1,024,992	$ 642,407
Net income per share - basic	$ 3.64	$ 2.53	$ 9.66	$ 6.14
Net income per share - diluted	$ 3.32	$ 2.27	$ 8.84	$ 5.51
Weighted average shares outstanding - basic	106,706	104,833	106,108	104,586
Weighted average shares outstanding - diluted	117,028	116,466	115,994	116,567
Statements of Comprehensive Income				
Net income	$ 388,317	$ 264,804	$ 1,024,992	$ 642,407
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on marketable securities	21,485	(8,103)	36,645	(11,471)
Unrealized gain on cash flow hedges	2	—	30	—
Comprehensive income	$ 409,804	$ 256,701	$ 1,061,667	$ 630,936

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

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

	Nine Months Ended September 30,	
	2017	**2016**
Cash flows from operating activities:		
Net income	$ 1,024,992	$ 642,407
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	110,960	75,845
Non-cash compensation expense	380,144	405,320
Other non-cash charges and expenses, net	44,016	13,586
Deferred taxes	(108,242)	(190,327)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer, and trade accounts receivable	(359,829)	(176,079)
Increase in inventories	(235,645)	(99,706)
(Increase) decrease in prepaid expenses and other assets	(28,209)	34,857
(Decrease) increase in deferred revenue	(59,116)	282,176
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(28,908)	107,438
Total adjustments	(284,829)	453,110
Net cash provided by operating activities	740,163	1,095,517
Cash flows from investing activities:		
Purchases of marketable securities	(883,748)	(606,153)
Sales or maturities of marketable securities	379,275	192,091
Capital expenditures	(164,963)	(361,486)
Net cash used in investing activities	(669,436)	(775,548)
Cash flows from financing activities:		
Proceeds in connection with capital and facility lease obligations	57,000	5,085
Payments in connection with capital and facility lease obligations	(19,925)	(1,853)
Repayments of convertible senior notes	—	(12,650)
Payments in connection with reduction of outstanding warrants	—	(242,117)
Proceeds from issuance of Common Stock	226,892	89,777
Payments in connection with Common Stock tendered for employee tax obligations	(77,832)	(46,954)
Net cash provided by (used in) financing activities	186,135	(208,712)
Net increase in cash and cash equivalents	256,862	111,257
Cash and cash equivalents at beginning of period	535,203	809,102
Cash and cash equivalents at end of period	$ 792,065	$ 920,359

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

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

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim period are not necessarily indicative of the results for the full year. The December 31, 2016 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

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

2. Product Sales

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net Product Sales in the United States	**2017**	**2016**	**2017**	**2016**
EYLEA®	$ 953,279	$ 853,588	$ 2,727,132	$ 2,465,369
ARCALYST®	4,088	3,880	12,613	10,500
Net Product Sales	$ 957,367	$ 857,468	$ 2,739,745	$ 2,475,869

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the three and nine months ended September 30, 2017 and 2016. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Besse Medical, a subsidiary of AmerisourceBergen Corporation	51%	54%	51%	56%
McKesson Corporation	29%	28%	29%	28%
Curascript SD Specialty Distribution, a subsidiary of Express Scripts	19%	17%	19%	15%

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

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions and credits/payments for these sales-related deductions during the nine months ended September 30, 2017 and 2016.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2016	$ 12,712	$ 29,465	$ 3,674	$ 45,851
Provisions	121,599	140,860	33,518	295,977
Credits/payments	(108,811)	(136,272)	(21,444)	(266,527)
Balance as of September 30, 2017	$ 25,500	$ 34,053	$ 15,748	$ 75,301
Balance as of December 31, 2015	$ 6,419	$ 48,313	$ 517	$ 55,249
Provisions	63,510	113,755	22,812	200,077
Credits/payments	(62,503)	(135,483)	(19,587)	(217,573)
Balance as of September 30, 2016	$ 7,426	$ 26,585	$ 3,742	$ 37,753

3. Collaboration Agreements

a. Sanofi

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Sanofi Collaboration Revenue	**2017**	**2016**	**2017**	**2016**
Antibody:				
Reimbursement of Regeneron research and development expenses	$ 128,539	$ 131,389	$ 421,056	$ 469,223
Reimbursement of Regeneron commercialization-related expenses	90,339	64,418	251,002	213,957
Regeneron's share of losses in connection with commercialization of antibodies	(98,315)	(112,001)	(328,998)	(333,530)
Other	41,848	4,360	84,338	19,999
Total Antibody	162,411	88,166	427,398	369,649
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses	61,649	36,226	188,408	97,851
Other	21,115	20,000	61,864	60,000
Total Immuno-oncology	82,764	56,226	250,272	157,851
	$ 245,175	$ 144,392	$ 677,670	$ 527,500

Antibodies

In November 2007, the Company entered into a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). The Antibody Collaboration is governed by the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended). Pursuant to the Antibody Discovery Agreement, Sanofi agreed to fund up to $130.0 million of the Company's research activities in 2017. The Company's Antibody Discovery Agreement with Sanofi will end on December 31, 2017 without any extension and, therefore, funding from Sanofi under the Antibody Discovery Agreement will cease after 2017.

Under the License and Collaboration Agreement, agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. Consequently, during the three months ended September 30, 2017 and 2016, the Company recognized as research and development expense $22.6 million and $27.9 million, respectively, and during the nine months ended September 30, 2017 and 2016, the Company recognized as research and development expense $68.2 million and $80.2 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent®, Kevzara® (sarilumab), and Dupixent® (dupilumab).

"Reimbursement of Regeneron commercialization-related expenses" in the table above represents reimbursement of internal and external costs in connection with commercializing Praluent, Kevzara, and Dupixent. During the same periods that the Company recorded reimbursements from Sanofi related to the Company's commercialization expenses, the Company also recorded its share of losses in connection with the companies commercializing Praluent, Kevzara, and Dupixent within Sanofi collaboration revenue.

In March 2017, the U.S. Food and Drug Administration ("FDA") approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis, and in September 2017, the European Commission granted marketing authorization for Dupixent for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. In May 2017, the FDA approved Kevzara for the treatment of adult patients with moderately to severely active rheumatoid arthritis, and in June 2017, the European Commission granted marketing authorization for Kevzara for the treatment of rheumatoid arthritis in adult patients.

Immuno-Oncology

In July 2015, the Company and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement ("IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). Pursuant to the IO Discovery Agreement, Sanofi will reimburse the Company for up to $200.0 million in 2017 to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Under the terms of the IO License and Collaboration Agreement, the parties are co-developing the Company's antibody product candidate targeting the receptor known as programmed cell death protein 1, or PD-1 ("cemiplimab"). The parties share equally, on an ongoing basis, development expenses for cemiplimab.

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 by the Company as deferred revenue, and is being recognized ratably as revenue over the related performance period.

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

b. Bayer

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Bayer Collaboration Revenue	**2017**	**2016**	**2017**	**2016**
EYLEA:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 205,367	$ 170,854	$ 571,126	$ 484,181
Reimbursement of Regeneron EYLEA development expenses	6,053	2,219	10,833	7,186
Other	15,714	6,077	36,910	45,924
Total EYLEA	227,134	179,150	618,869	537,291
Ang2 antibody and PDGFR-beta antibody:				
Reimbursement of development expenses	7,325	7,433	15,614	14,165
Other	2,166	4,715	6,436	11,330
Total Ang2 antibody and PDGFR-beta antibody	9,491	12,148	22,050	25,495
	$ 236,625	$ 191,298	$ 640,919	$ 562,786

EYLEA outside the United States

Under the terms of the license and collaboration agreement with Bayer for the global development and commercialization outside the United States 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, the Company is entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales. In addition, the Company and Bayer share the funding of agreed-upon EYLEA development costs.

Ang2 antibody outside the United States

In March 2016, the Company entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to angiopoietin-2 (Ang2), including REGN910-3 (Ang2 in combination with aflibercept), for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to the Company and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. The $50.0 million up-front payment was initially recorded as deferred revenue, and is being recognized ratably as revenue over the related performance period.

PDGFR-beta antibody outside the United States

In 2014, the Company entered into a license and collaboration agreement with Bayer governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), including REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept. The agreement provided that the Company would conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer would have a right to opt-in to license and collaborate on further development and commercialization outside the United States. Effective in the first quarter of 2017, the Company discontinued clinical development of REGN2176-3, and on July 31, 2017, the Company and Bayer agreed to terminate this collaboration agreement.

c. Mitsubishi Tanabe Pharma

In 2015, the Company and Mitsubishi Tanabe Pharma Corporation ("MTPC") entered into a collaboration agreement providing MTPC with development and commercial rights to fasinumab, the Company's nerve growth factor antibody in late-stage clinical development, in certain Asian countries. In connection with the agreement, MTPC made a $10.0 million non-refundable up-front

payment, which was initially recorded as deferred revenue, and is being recognized ratably as revenue over the related performance period. In the first quarter of 2016, MTPC made additional payments totaling $60.0 million to the Company, which were recorded as deferred revenue and are being recognized ratably as revenue over the same performance period as the up-front payment.

In the second quarter of 2017, the Company earned, and recognized as a substantive milestone, a $30.0 million development milestone from MTPC upon initiation of a Phase 3 trial.

d. Teva

In September 2016, the Company and Teva entered into a collaboration agreement (the "Teva Collaboration Agreement") to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to the Company's collaboration agreement with MTPC (as described above). In connection with the Teva Collaboration Agreement, Teva made a $250.0 million non-refundable up-front payment in September 2016. The Company leads global development activities, and the parties share development costs equally on an ongoing basis. The $250.0 million up-front payment was initially recorded as deferred revenue, and is being recognized ratably as revenue over the related performance period.

The Company recognized revenue of $40.2 million and $141.0 million for the three and nine months ended September 30, 2017, respectively, and $5.2 million for the three months ended September 30, 2016, in connection with the Teva Collaboration Agreement. In the second quarter of 2017, the Company earned, and recognized as a substantive milestone, a $25.0 million development milestone from Teva upon initiation of a Phase 3 trial.

e. Intellia Therapeutics

In April 2016, the Company entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas gene-editing technology for *in vivo* therapeutic development. The Company collaborates with Intellia to conduct research for the discovery, development, and commercialization of new therapies, in addition to the research and technology development of the CRISPR/Cas platform. In connection with the execution of the agreement, the Company made a $75.0 million up-front payment, which was recorded as research and development expense in the second quarter of 2016. In May 2016, Intellia completed an initial public offering ("IPO") of its common stock; as part of the concurrent private placement, the Company purchased $50.0 million of Intellia common stock.

e. Adicet Bio

In July 2016, the Company entered into a license and collaboration agreement with Adicet Bio, Inc., a privately held company, to develop next-generation engineered immune-cell therapeutics with fully human chimeric antigen receptors ("CARs") and T-cell receptors ("TCRs") directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells. The Company collaborates with Adicet to identify and validate targets, and to develop a pipeline of engineered immune-cell therapeutics for selected targets. In connection with the execution of the agreement, the Company made a $25.0 million up-front payment to Adicet, which was recorded as research and development expense in the third quarter of 2016, and is obligated to provide Adicet with research funding over the course of a five-year research term.

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

4. 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Net income - basic	$ 388,317	$ 264,804	$ 1,024,992	$ 642,407
Effect of dilutive securities:				
Convertible senior notes - interest expense and amortization of discount and note issuance costs	—	—	—	397
Net income - diluted	$ 388,317	$ 264,804	$ 1,024,992	$ 642,804
(Shares in thousands)				
Weighted average shares - basic	106,706	104,833	106,108	104,586
Effect of dilutive securities:				
Stock options	9,809	10,156	9,386	10,340
Restricted stock	513	479	500	474
Convertible senior notes	—	—	—	81
Warrants	—	998	—	1,086
Dilutive potential shares	10,322	11,633	9,886	11,981
Weighted average shares - diluted	117,028	116,466	115,994	116,567
Net income per share - basic	$ 3.64	$ 2.53	$ 9.66	$ 6.14
Net income per share - diluted	$ 3.32	$ 2.27	$ 8.84	$ 5.51

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(Shares in thousands)	**2017**	**2016**	**2017**	**2016**
Stock options	4,515	7,687	8,892	7,842
Restricted stock	—	19	—	19
Convertible senior notes	—	3	—	—

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

5. Marketable Securities

Marketable securities as of September 30, 2017 and December 31, 2016 consist of both debt securities of investment grade issuers as well as equity securities.

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

As of September 30, 2017	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate bonds	$ 1,564,391	$ 2,789	$ (2,691)	$ 1,564,489
U.S. government and government agency obligations	189,647	56	(645)	189,058
Municipal bonds	4,614	—	(8)	4,606
Commercial paper	61,464	—	—	61,464
Certificates of deposit	6,525	—	—	6,525
Equity securities	57,251	30,789	—	88,040
	$ 1,883,892	$ 33,634	$ (3,344)	$ 1,914,182
As of December 31, 2016				
Corporate bonds	$ 1,076,964	$ 630	$ (4,743)	$ 1,072,851
U.S. government and government agency obligations	132,923	58	(641)	132,340
Municipal bonds	7,663	1	(20)	7,644
Commercial paper	63,074	1	—	63,075
Certificates of deposit	42,612	—	—	42,612
Equity securities	57,251	5,551	(13,583)	49,219
	$ 1,380,487	$ 6,241	$ (18,987)	$ 1,367,741

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of September 30, 2017 mature at various dates through September 2022. The fair values of debt security investments by contractual maturity consist of the following:

	September 30, 2017	December 31, 2016
Maturities within one year	$ 586,879	$ 503,481
Maturities after one year through five years	1,239,263	815,041
	$ 1,826,142	$ 1,318,522

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

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

	Less than 12 Months		12 Months or Greater		Total	
As of September 30, 2017	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 675,374	$ (2,111)	$ 110,545	$ (580)	$ 785,919	$ (2,691)
U.S. government and government agency obligations	141,393	(591)	6,943	(54)	148,336	(645)
Municipal bonds	4,105	(8)	—	—	4,105	(8)
	$ 820,872	$ (2,710)	$ 117,488	$ (634)	$ 938,360	$ (3,344)
As of December 31, 2016						
Corporate bonds	$ 759,222	$ (4,685)	$ 36,407	$ (58)	$ 795,629	$ (4,743)
U.S. government and government agency obligations	81,170	(641)	—	—	81,170	(641)
Municipal bonds	7,141	(20)	—	—	7,141	(20)
Equity securities	36,417	(13,583)	—	—	36,417	(13,583)
	$ 883,950	$ (18,929)	$ 36,407	$ (58)	$ 920,357	$ (18,987)

There were no realized losses on sales of marketable securities, and realized gains were not material, for the three and nine months ended September 30, 2017. Realized gains and losses on sales of marketable securities were not material for the three and nine months ended September 30, 2016.

As it relates to marketable securities, for the three and nine months ended September 30, 2017 and 2016, amounts reclassified from accumulated other comprehensive income (loss) into other (expense) income, net were related to realized gains and losses on sales.

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6. Fair Value Measurements

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

		Fair Value Measurements at Reporting Date Using	
As of September 30, 2017	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**
Available-for-sale marketable securities:			
Corporate bonds	$ 1,564,489	—	$ 1,564,489
U.S. government and government agency obligations	189,058	—	189,058
Municipal bonds	4,606	—	4,606
Commercial paper	61,464	—	61,464
Certificates of deposit	6,525	—	6,525
Equity securities	88,040	$ 88,040	—
	$ 1,914,182	$ 88,040	$ 1,826,142
As of December 31, 2016			
Available-for-sale marketable securities:			
Corporate bonds	$ 1,072,851	—	$ 1,072,851
U.S. government and government agency obligations	132,340	—	132,340
Municipal bonds	7,644	—	7,644
Commercial paper	63,075	—	63,075
Certificates of deposit	42,612	—	42,612
Equity securities	49,219	$ 49,219	—
	$ 1,367,741	$ 49,219	$ 1,318,522

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and nine months ended September 30, 2017 and 2016.

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and nine months ended September 30, 2017 and 2016. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the nine months ended September 30, 2017 and 2016.

The fair value of interest rate swap and interest rate cap contracts, which were recorded within other assets (non-current) and other long-term liabilities, was not material as of September 30, 2017 (see Note 11). The fair value of these contracts was determined based on Level 2 inputs, using significant inputs that are observable either directly or indirectly, including London Interbank Offered Rate ("LIBOR") and interest rate swap rates.

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7. Inventories

Inventories consist of the following:

	September 30, 2017	December 31, 2016
Raw materials	$ 187,029	$ 92,287
Work-in-process	217,448	202,301
Finished goods	23,958	13,334
Deferred costs	213,153	91,434
	$ 641,588	$ 399,356

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2017	December 31, 2016
Accounts payable	$ 153,946	$ 134,984
Accrued payroll and related costs	166,102	153,086
Accrued clinical trial expenses	119,608	91,753
Accrued sales-related charges, deductions, and royalties	167,467	159,985
Income taxes payable	126,612	235,776
Other accrued expenses and liabilities	84,691	103,512
	$ 818,426	$ 879,096

9. Debt

a. Convertible Debt

In the first nine months of 2016, the Company settled conversion obligations for $12.7 million principal amount of the Company's convertible senior notes (the "Notes") that was previously surrendered for conversion. Consequently, in the first nine months of 2016, the Company paid $12.7 million in cash and issued 118,822 shares of Common Stock. In addition, the Company allocated $47.1 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholders' equity. The loss on the debt extinguishment in connection with the Notes that were surrendered for conversion during the first nine months of 2016 was not material. As a result of these Note conversions, in the first nine months of 2016, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 118,808 shares of Common Stock, which was approximately equal to the number of shares the Company was required to issue to settle the non-cash portion of the related Note conversions. The Company recorded the cost of the shares received, or $10.0 million, as Treasury Stock during the first nine months of 2016.

Warrant Transactions

In November 2015, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $535.00 per share, during the period starting on November 16,

2015 and ending no later than February 9, 2016. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. As a result of the warrant holder closing out a portion of its hedge position in the first quarter of 2016, the Company paid a total of $135.2 million to reduce the number of warrants held by such warrant holder by 360,406.

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

b. Credit Facility

In 2015, the Company entered into an agreement with a syndicate of lenders which provides for a $750.0 million senior unsecured five-year revolving credit facility. As of September 30, 2017, the Company had no borrowings outstanding under the credit facility and was in compliance with all credit facility covenants.

10. Leases

The Company leases laboratory and office facilities in Tarrytown, New York (the "Tarrytown Leases"). Prior to December 30, 2016, certain of the premises under the Tarrytown Leases had been accounted for as operating leases, while for certain other buildings the Company leased, the Company was deemed, in substance, to be the owner of the landlord's buildings (collectively, the "Build-to-Suit Buildings") in accordance with the application of FASB authoritative guidance. On December 30, 2016, the Company entered into a Purchase Agreement with BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC (collectively, "BMR"), pursuant to which the Company agreed to purchase BMR's Tarrytown, New York facilities (the "Facility") for a purchase price of $720.0 million. The Company occupies a significant portion of the Facility, with the remaining rentable area under leases to third-party tenants. In accordance with the terms of the Purchase Agreement, the Company paid $57.0 million toward the purchase price to BMR in December 2016.

Upon entering into the December 30, 2016 Purchase Agreement with BMR, the premises under the Company's Tarrytown Leases that were historically accounted for as operating leases were deemed to be modified, as the Company now had the option to purchase the Facility under terms that made it reasonably assured to be exercised. Consequently, the leases for such premises were re-classified as a capital lease upon execution of the Purchase Agreement, and a proportionate amount of the $57.0 million payment was recorded as reduction of the initial capital lease liability. The execution of the Purchase Agreement did not impact the balance sheet classification for the Build-to-Suit Buildings; however, a proportionate amount of the $57.0 million payment was recorded as a reduction to the related facility lease obligation.

On March 3, 2017, the Company entered into a Participation Agreement with Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively, the "Participants"). The Participation Agreement provided for lease financing in connection with the acquisition by BAL of the Facility and the Company's lease of the Facility from BAL. On March 3, 2017, the right to take title to the Facility under the Purchase Agreement was assigned by the Company to BAL, and the Participants advanced $720.0 million, which was used by BAL to finance the purchase price for the Facility and to reimburse the Company for the $57.0 million payment made to BMR in December 2016. The $57.0 million reimbursement was recorded by the Company in March 2017 as an increase to capital and facility lease obligations in amounts equal to those initially recorded upon making such payment to BMR in December 2016.

On March 3, 2017, the Company entered into a lease agreement (the "Lease") with BAL, pursuant to which the Company has leased the Facility from BAL for a five-year term. As a result of entering into the lease agreement, certain parts of the Facility became subleased from the Company by existing third-party tenants. The Lease requires the Company to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. The Company is also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month LIBOR, plus an applicable margin that varies with the Company’s debt rating and total leverage ratio.

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

As a result of entering into the lease agreement with BAL, the premises that were classified as a capital lease as of December 31, 2016 were reassessed. As described above, the Company has the option to purchase the Facility, and as a result, the Company is deemed to have continuing involvement in such premises. Accordingly, these premises continue to be classified as a capital lease, with the related property, plant, and equipment and capital lease liability remaining on the Company's Condensed Consolidated Balance Sheet. In addition, as described above, upon entering into the lease agreement, the Company began to lease space occupied by third-party tenants. The lease of such premises is also classified as a capital lease. The execution of the March 2017 lease agreement did not impact the balance sheet classification for the Build-to-Suit Buildings. However, during the first nine months of 2017, the Company recorded a $30.1 million loss on extinguishment of debt associated with the Build-to-Suit Buildings, and a corresponding decrease to property, plant and equipment. In the aggregate, the Company recorded $720.0 million of capital and facility lease obligations upon execution of the lease agreement for the Facility.

The Participation Agreement and the Lease contain financial and operating covenants, which are substantially similar to the covenants set forth in the Company's credit facility (see Note 9). The Company was in compliance with all covenants of the Participation Agreement and the Lease as of September 30, 2017.

11. Derivative Instruments and Hedging Activities

The Company is exposed to market fluctuations in interest rates, including those in connection with its March 2017 lease agreement (see Note 10). During the three and nine months ended September 30, 2017, the Company entered into interest rate swap and interest rate cap agreements to manage a portion of such interest rate risk. All of the Company’s derivative instruments are utilized for risk management purposes, and are not used for trading or speculative purposes.

The Company's derivative instruments are designated as cash flow hedges for accounting purposes. Since the specific terms of the derivative instruments match those of the item being hedged, the derivative instruments are deemed to be highly effective in offsetting the changes in cash flows of the hedged item. As such, changes in the fair value of these derivatives are recorded in accumulated other comprehensive income (loss) until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. The Company would record any gain or loss related to the ineffectiveness directly to earnings.

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

The following table summarizes the notional amounts of the Company's outstanding interest rate swap and cap agreements as of September 30, 2017:

	Notional Amount	
Interest rate swap contracts	$	75,000
Interest rate cap contracts	$	75,000

As it relates to cash flow hedges, for the three and nine months ended September 30, 2017, amounts of gains and losses recognized in other comprehensive income (loss), and amounts reclassified from accumulated other comprehensive income (loss) into interest expense, net, were not material. As of September 30, 2017, the amounts expected to be reclassified out of accumulated other comprehensive income into interest expense over the next 12 months is not expected to be material. For the three and nine months ended September 30, 2017, there were no gains or losses recorded related to the ineffective portion of the derivative instruments.

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12. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of $177.3 million and $101.1 million for the three months ended September 30, 2017 and 2016, respectively, and $498.8 million and $345.9 million for the nine months ended September 30, 2017 and 2016, respectively. The Company's effective tax rate was 31.3% and 27.6% for the three months ended September 30, 2017 and 2016, respectively, and 32.7% and 35.0% for the nine months ended September 30, 2017 and 2016, respectively. The Company's effective tax rate for the three and nine months ended September 30, 2017 and 2016 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for research activities, offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. The Company's effective tax rate for the three months ended September 30, 2016 was also positively impacted by changes to tax reserves.

The Company also recorded an income tax provision of $6.4 million and $6.5 million in its Statement of Comprehensive Income for the three and nine months ended September 30, 2017, respectively, primarily related to unrealized gains on available-for-sale marketable securities. The Company recorded an income tax benefit of $3.3 million in its Statement of Comprehensive Income for the nine months ended September 30, 2016 primarily related to unrealized losses on available-for-sale marketable securities; such amount for the three months ended September 30, 2016 was not material.

13. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable and accrued expenses as of September 30, 2017 and December 31, 2016 were $24.5 million and $28.2 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses as of September 30, 2016 and December 31, 2015 were $33.9 million and $50.7 million, respectively, of accrued capital expenditures.

The Company recognized an additional capital lease obligation of $201.2 million in connection with the Company's lease of additional premises at its Tarrytown, New York facility during the nine months ended September 30, 2017 (see Note 10). No such amount was recognized during the nine months ended September 30, 2016.

14. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted.

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

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

Proceedings Relating to Praluent (alirocumab) Injection

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

In the United States, Amgen has asserted a number of U.S. patents, which were subsequently narrowed to U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and seeks a permanent injunction to prevent the Company and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, "Commercializing") Praluent. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. A jury trial in this litigation was held in the United States District Court for the District of Delaware (the "District Court") from March 8 to March 16, 2016. During the course of the trial, the District Court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of the Company and the Sanofi defendants that there was no willful infringement of the asserted patent claims by the Company or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On January 3, 2017, the District Court issued a final opinion and judgment, denying the Company and the Sanofi defendants' motions for new trial and judgment as a matter of law. The District Court also denied as moot Amgen's motion to strike the Company and the Sanofi defendants' request to obtain a judgment as a matter of law, which allowed the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") to address the Company and the Sanofi defendants' patent invalidity arguments on appeal. On January 12, 2017, the Company and the Sanofi defendants filed a notice of appeal with the Federal Circuit. On April 19, 2017, the District Court granted Amgen's motion to amend the judgment on an accounting of supplemental damages and enhancement of such damages if deemed appropriate, but deferred the order until after the Federal Circuit issued a decision on the appeal. Oral argument on the appeal was held on June 6, 2017. On October 5, 2017, the Federal Circuit reversed in part the District Court's decision, remanded for a new trial on the issues of written description and enablement, and, as discussed below, vacated the District Court's permanent injunction. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious. The Federal Circuit further concluded the Company and the Sanofi defendants were not entitled to judgment as a matter of law on the issues of written description and enablement on this record.

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

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

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

On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie, and Sanofi Chimie (subsequently added as a defendant). Amgen is seeking the prohibition of allegedly infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time. On April 10, 2017, the Company and the Sanofi parties filed briefs seeking invalidation of certain of the claims of the '124 Patent, and Amgen filed a response on July 28, 2017. Oral hearing on this infringement lawsuit is currently scheduled for June 29, 2018.

The '124 Patent is also subject to opposition proceedings in the European Patent Office seeking to invalidate certain of its claims, which were initiated by the Company on November 24, 2016.

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 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.

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

Proceedings Relating to Dupixent (dupilumab) Injection

On March 20, 2017, the Company, Sanofi-Aventis U.S. LLC, and Genzyme Corporation filed a complaint 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 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. The Additional IPR Petitions are still pending.

On April 5, 2017, Immunex Corporation filed a complaint 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 jury trial has been scheduled to start on March 19, 2019.

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

Proceedings Relating to Shareholder Derivative Claims

On December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the then current and certain former non-employee members of the Company's board of directors, the Chairman of the board of directors, the Company's Chief Executive Officer, and the Company's Chief Scientific Officer as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2013 and 2014. The complaint seeks damages in favor of the Company for the alleged breaches of fiduciary duties and unjust enrichment; changes to Regeneron's corporate governance and internal procedures; invalidation of the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan with respect to the individual defendants' compensation and a shareholder vote regarding the individual defendants' equity compensation; equitable relief, including an equitable accounting with disgorgement; and award of the costs of the action, including attorneys' fees. On June 28, 2017, the court dismissed the plaintiff's claims with respect to certain compensation awarded in 2013 but denied the defendants' motion to dismiss the other claims set forth in the complaint.

On or about December 15, 2015, the Company received a shareholder litigation demand upon the Company's board of directors made by a purported Regeneron shareholder. On or about November 3, 2017, the Company received a second shareholder litigation demand upon the Company's board of directors made by another purported Regeneron shareholder, which is substantially similar to the December 15, 2015 shareholder litigation demand. The demands assert that the then current and certain former non-employee members of the board of directors and the Chairman of the board of directors excessively compensated themselves in 2013 and 2014. The demands request that the board of directors investigate and bring legal action against these directors for breach of fiduciary duty, unjust enrichment, and corporate waste, and implement internal controls and systems designed to prohibit and

prevent similar actions in the future. The Company's board of directors is evaluating the impact of the court's decision pertaining to the motion to dismiss discussed above on the board's response to these demands.

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

Department of Justice Investigation

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

15. Recently Issued Accounting Standards

In May 2014, the FASB issued Accounting Standards Update 2014-09 ("ASU 2014-09"), *Revenue from Contracts with Customers*, which, along with subsequent amendments to ASU 2014-09 issued by the FASB, will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. The new standard will be effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption is permitted, but no earlier than 2017 for calendar year-end entities. The standard allows for two transition methods - retrospectively to each prior reporting period presented (full retrospective method) or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption (modified retrospective method). The Company has substantially completed its impact assessment, and does not currently expect the new standard to have a material impact on total revenues. However, substantive development milestones, which were previously recognized in the period when the milestone was achieved, will be recognized over the remaining performance period under the new standard. In connection with adopting the new standard, the Company does not anticipate implementing changes to its systems or internal controls. The Company expects to adopt the standard using the modified retrospective method, and continues to evaluate the impact of the new guidance on its financial statement disclosures.

In January 2016, the FASB issued Accounting Standards Update 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The amendments require equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The implementation of the amendments is expected to increase the volatility of the Company's net income, as the Company holds publicly traded equity investments; however, the Company is not able to estimate the impact of adopting these amendments, as the significance of the impact will depend on the Company's equity investment balance upon adoption.

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

In August 2017, the FASB issued Accounting Standard Update 2017-12, *Derivatives and Hedging: Targeted Improvements to Accounting for Hedging Activities*. The amendments expand and refine hedge accounting for both financial and non-financial risk components, align the recognition and presentation of the effects of hedging instruments and hedge items in the financial statements, and include certain targeted improvements to ease the application of current guidance related to the assessment of hedge effectiveness. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company does not expect the implementation of the amendments to have an impact on the Company's financial statements in connection with its current derivative instruments.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, cemiplimab, and fasinumab; the likelihood and timing of achieving any of our anticipated clinical development milestones; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation EYLEA, Dupixent, Praluent, Kevzara, cemiplimab, and fasinumab; the extent to which the results from the research and development programs conducted by us or our collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA, Dupixent, Praluent, 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 our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; the ability of our collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to our products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation proceedings relating to Dupixent and Praluent described further in Part II, Item 1. "Legal Proceedings" of this report. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, 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.

Overview

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 disease, heart disease, allergic and inflammatory diseases, pain, cancer, and infectious and rare diseases.

Our total revenues were $1,500.7 million in the third quarter and $4,289.8 million in the first nine months of 2017, compared to $1,220.1 million in the third quarter and $3,633.6 million in the first nine months of 2016. Our net income was $388.3 million, or $3.32 per diluted share, in the third quarter and $1,025.0 million, or $8.84 per diluted share, in the first nine months of 2017, compared to net income of $264.8 million, or $2.27 per diluted share, in the third quarter and $642.4 million, or $5.51 per diluted share, in the first nine months of 2016. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have six products that have received marketing approval:

- **EYLEA (aflibercept) Injection**, known in the scientific literature as VEGF Trap-Eye, is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD), diabetic macular edema (DME), macular edema following retinal vein occlusion (RVO), which includes macular edema following central retinal vein occlusion (CRVO) and macular edema following branch retinal vein occlusion (BRVO). EYLEA is also available in the EU, Japan, and certain other countries outside the United States for the treatment of myopic choroidal neovascularization (mCNV) and in the United States for the treatment of diabetic retinopathy in patients with DME. Bayer has additional regulatory applications for EYLEA for various indications pending in other countries, including EYLEA for the treatment of wet AMD and DME in China.

  We are collaborating with Bayer on the global development and commercialization of EYLEA outside the United States. Bayer markets, and records revenue from sales of EYLEA outside the United States, where, for countries other than Japan, the companies share equally the profits and losses from sales of EYLEA. In Japan, we are entitled to receive a percentage of the sales of EYLEA. We maintain exclusive rights to EYLEA in the United States and are entitled to all profits from such sales.

- **Dupixent (dupilumab) Injection.** On March 28, 2017, the the U.S. Food and Drug Administration (FDA) approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The launch of Dupixent commenced in March following the FDA approval. Sanofi records product sales for Dupixent, and we and Sanofi share profits and losses from sales of Dupixent. We have exercised our option to co-promote Dupixent in the United States and thus far have not exercised our option to co-promote Dupixent outside the United States.

  In September 2017, the European Commission granted marketing authorization for Dupixent for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. In addition, in the first quarter of 2017, an application for marketing approval for Dupixent was submitted in Japan. Sanofi has additional regulatory applications for Dupixent for use in adult patients with atopic dermatitis pending in other countries.

- **Praluent (alirocumab) Injection** is available in the United States where it is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol. Praluent is also available in certain European countries and in Japan. In April 2017, the FDA approved the supplemental Biologics License Application (sBLA) for a once-monthly (every four weeks), 300 mg dose of Praluent. In July 2017, the FDA approved the sBLA for Praluent's time out of refrigeration, which was increased from 24 hours to 30 days. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent. See Part II, Item 1. "Legal Proceedings" for information regarding the patent infringement proceedings relating to Praluent, which may impact Praluent's commercial availability in certain jurisdictions.

  Sanofi records product sales for Praluent, and we and Sanofi share profits and losses from sales of Praluent. We have exercised our option to co-promote Praluent in the United States and thus far have not exercised our option to co-promote Praluent outside the United States. Sanofi has additional regulatory applications for Praluent pending in other countries.

- **Kevzara (sarilumab) Solution for Subcutaneous Injection**. In January 2017, Health Canada approved Kevzara for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have an inadequate response to or intolerance to one or more biologic or non-biologic disease modifying anti-rheumatic drugs (DMARDs). This was the first approval of Kevzara worldwide. On May 22, 2017, the FDA approved Kevzara for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have an inadequate response or intolerance to one or more DMARDs. In June 2017, the European Commission granted marketing authorization for Kevzara in combination with methotrexate (MTX) for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs; Kevzara may be used as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. In September 2017, the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan approved Kevzara for the treatment of adult patients with rheumatoid arthritis who have had an inadequate response to conventional treatments.

  Sanofi records product sales for Kevzara, and we and Sanofi share profits and losses from sales of Kevzara. We have exercised our option to co-promote Kevzara in the United States and thus far have not exercised our option to co-promote Kevzara outside the United States. Sanofi has additional regulatory applications for Kevzara for RA pending in other countries.

- **ARCALYST® (rilonacept) Injection for Subcutaneous Use** is available in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 12 years and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

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

Marketed Products

Net Product Sales of Regeneron-Discovered Products[1]	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2017	2016	2017	2016
EYLEA in the United States	$ 953.3	$ 853.6	$ 2,727.1	$ 2,465.4
ARCALYST	4.1	3.9	12.6	10.5
Net product sales recorded by Regeneron	$ 957.4	$ 857.5	$ 2,739.7	$ 2,475.9
EYLEA outside of the United States[1]	$ 563.7	$ 470.8	$ 1,590.0	$ 1,375.9
EYLEA global	$ 1,517.0	$ 1,324.4	$ 4,317.1	$ 3,841.3
Global net product sales recorded by Sanofi[1]:				
Praluent in the United States	$ 31.8	$ 31.6	$ 89.8	$ 61.9
Praluent outside of the United States	17.6	6.6	41.6	13.8
Praluent global	49.4	38.2	131.4	75.7
Dupixent	88.9	—	117.6	—
Kevzara	3.0	—	3.8	—
ZALTRAP	21.7	18.0	58.6	56.0
Net product sales recorded by Sanofi	$ 163.0	$ 56.2	$ 311.4	$ 131.7

[1] As described in the "Overview" section above, Bayer records net product sales of EYLEA outside the United States and Sanofi records global net product sales of Praluent, Dupixent, Kevzara, and ZALTRAP.

Programs in Clinical Development

We have 16 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and fully human monoclonal antibody product candidates, as summarized below. In addition to the product candidates in clinical development described below, we have ongoing studies for our marketed products. Each of the antibodies in the table below was generated using our *VelocImmune®* technology. There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, and changes in the competitive landscape affecting a product candidate. Refer to Part II, Item 1A, "Risk Factors" for a description of these and other risks and uncertainties that may affect our clinical programs.

Trap-based Clinical Program

EYLEA
In Phase 3 clinical development for the treatment of non-proliferative diabetic retinopathy (NPDR) in patients without DME (we are developing independently). As described below, aflibercept is also being studied in combination with nesvacumab, an antibody to angiopoietin-2 (Ang2) (in collaboration with Bayer).

Antibody-based Clinical Programs in Collaboration with Sanofi
Dupixent (dupilumab)
Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in pediatric patients ages 6 to 11 (Phase 2), asthma in adults and adolescents (Phase 3), nasal polyps (Phase 3), and eosinophilic esophagitis (EoE) (Phase 2). Phase 3 study in atopic dermatitis in adolescents (12-17 years of age) initiated in the first quarter of 2017. Phase 3 study in asthma in pediatrics (6-11 years of age) initiated in the second quarter of 2017. In the third quarter of 2017, the FDA granted orphan drug designation for the treatment of EoE.
Praluent
Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events. In the second quarter of 2017, the FDA granted orphan drug designation for the treatment of homozygous familial hypercholesterolemia (HoFH). Phase 3 study in HoFH initiated in the fourth quarter of 2017.
Kevzara (sarilumab)
Antibody to the interleukin-6 receptor (IL-6R). In clinical development in Polyarticular-course Juvenile Idiopathic Arthritis (pcJIA) (Phase 2).
Cemiplimab (REGN2810)
Antibody to programmed cell death protein 1 (PD-1). In clinical development in solid tumors and advanced hematologic malignancies (Phase 1) and metastatic or locally advanced and unresectable cutaneous squamous cell carcinoma (CSCC) (pivotal Phase 2). Phase 3 study in first-line treatment for non-small cell lung cancer (NSCLC) and potentially pivotal Phase 2 study in basal cell carcinoma (BCC) initiated in the second quarter of 2017. Phase 3 study in cervical cancer initiated in the third quarter of 2017. Cemiplimab is also being studied in combination with other antibodies and treatments. In the third quarter of 2017, the FDA granted Breakthrough Therapy designation for the treatment of adults with metastatic CSCC and adults with locally advanced and unresectable CSCC.
REGN3500
Antibody to interleukin-33 (IL-33) being developed for inflammatory diseases. Phase 1 studies in patients with asthma initiated in the first half of 2017.
REGN3767
Antibody to Lymphocyte Activation Gene 3 (LAG-3) protein. In Phase 1 clinical development (administered alone or in combination with cemiplimab) in advanced malignancies.
Antibody-based Clinical Program in Collaboration with Bayer
Nesvacumab/aflibercept (REGN910-3)**
Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. In Phase 2 clinical development for the treatment of wet AMD and DME. Fast Track designation received from the FDA for the treatment of patients with wet AMD, DME, and diabetic retinopathy.
Antibody-based Clinical Program in Collaboration with Teva and Mitsubishi Tanabe Pharma
Fasinumab (REGN475)*
Antibody to Nerve Growth Factor (NGF). In Phase 3 clinical development in osteoarthritis of knee and hip. Phase 3 efficacy studies in osteoarthritis of the knee or hip initiated in the second and third quarters of 2017. Phase 2b study for chronic low back pain initiated in the first quarter of 2016, and placed on clinical hold by the FDA in October 2016.
Antibody-based Clinical Programs Developing Independently
Evinacumab (REGN1500)*
Antibody to Angptl-3. In Phase 2 clinical development for the treatment of HoFH and severe forms of hyperlipidemia. FDA granted orphan drug designation for the treatment of HoFH. In the first quarter of 2017, the FDA granted Breakthrough Therapy designation for the treatment of hypercholesterolemia in patients with HoFH.
Trevogrumab (REGN1033)*
Antibody to myostatin (GDF8). In Phase 1 in combination with REGN2477 for muscle-wasting diseases.
REGN1908-1909*
Antibody to Feld1. In Phase 1 clinical development for the treatment of an allergic disease.
REGN1979
Bispecific antibody against CD20 and CD3. In Phase 1 clinical development as monotherapy and in combination with cemiplimab in certain B-cell malignancies. In the second quarter of 2017, the FDA granted orphan drug designation in diffuse large B-cell lymphoma.
REGN3470-3471-3479***
Multi-antibody therapy to Ebola virus. In Phase 1 clinical development. FDA granted orphan drug designation for the treatment of Ebola virus infection.

Antibody-based Clinical Programs Developing Independently *(continued)*
REGN2477*
Antibody to Activin A being developed for Fibrodysplasia Ossificans Progressiva (FOP). FDA granted orphan drug designation for the treatment of FOP. In addition, in Phase 1 clinical development in combination with trevogrumab for muscle-wasting diseases. In the second quarter of 2017, the FDA granted Fast Track designation for the prevention and treatment of heterotopic ossification in patients with FOP.
REGN3918*
Antibody to complement 5 (C5) being developed for paroxysmal nocturnal hemoglobinuria (PNH). Phase 1 study in healthy volunteers initiated in the second quarter of 2017.

* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future global sales of the product candidate.

** Antibodies targeting the Ang2 receptor and ligand in ophthalmology were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future global sales of the product candidate and a potential development milestone.

*** Sanofi did not opt-in to the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate. We and the Biomedical Advanced Research Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) are parties to agreements (including an agreement executed in September 2017 - see "Other Programs" below for further information) whereby HHS provides certain funding to support research, development, and manufacturing of a monoclonal antibody therapy for the treatment of Ebola virus infection.

In the third quarter of 2017, we reported that a Phase 3 study evaluating suptavumab (REGN2222), an antibody to the Respiratory Syncytial Virus-F (RSV-F) protein, did not meet its primary endpoint of preventing medically-attended RSV infections in infants. Suptavumab did show signs of efficacy in a subgroup of patients. Adverse events were generally balanced between suptavumab and placebo. Further clinical development of suptavumab has been discontinued.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to combine that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to be an integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*® technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Clinical Programs - Ophthalmologic Diseases

EYLEA - Ophthalmologic Diseases

Overview

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet AMD, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results. Wet AMD, diabetic retinopathy (which includes DME), and RVO are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by neovascular proliferation and/or retinal edema.

EYLEA is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Diabetic Retinopathy

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

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

Neovascular Glaucoma

NVG is a secondary glaucoma triggered by the formation of new blood vessels (neovascularization) on the iris and the anterior chamber angle. Neovascularization restricts aqueous outflow and consequently elevates intraocular pressure (IOP). NVG is a serious condition that may lead to permanent loss of vision, a persistently painful eye, and, especially in the advanced stages, is unlikely to respond to treatment. NVG is caused by eye diseases leading to retinal ischemia, mainly CRVO, PDR, and ocular ischemic syndrome (OIS). NVG meets the criteria for an orphan indication in Japan where the estimated number of NVG patients is 30,000 to 40,000. A Phase 3 study for the treatment of NVG (in Japan) was completed in 2016 (in collaboration with Bayer).

Combination Product with Nesvacumab (REGN910-3)

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

Late-Stage Antibody-based Clinical Programs

Dupixent (dupilumab; IL-4R Antibody) for allergic and inflammatory conditions

Overview

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies atopic (allergic) dermatitis, asthma, nasal polyps, and eosinophilic esophagitis. Dupilumab is a fully human monoclonal antibody generated using our *VelocImmune* technology that is designed to bind to IL-4R alpha subunit and block signaling from both IL-4 and IL-13.

Atopic Dermatitis

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

In 2016, the Phase 3 LIBERTY AD CAFÉ study of Dupixent was initiated, investigating two dose regimens of Dupixent (300 mg weekly and 300 mg every two weeks) with concomitant topical corticosteroids in adult patients with moderate-to-severe atopic dermatitis who are inadequately controlled with or are intolerant to the broad immunosuppressant drug cyclosporine A (CSA), or when this treatment is medically inadvisable. The primary endpoint of this study was the proportion of patients with a 75% or greater improvement from baseline in their Eczema Area and Severity Index (EASI-75) score at 16 weeks. In April 2017, we and Sanofi announced that the results of the LIBERTY AD CAFÉ study were positive and demonstrated an acceptable safety profile. These results were submitted to the EMA and in September 2017, we and Sanofi presented the results at the annual European Academy of Dermatology and Venereology (EADV) Congress.

In March 2017, at the Annual Meeting of the American Academy of Dermatology, we and Sanofi presented additional detailed results from the Phase 3 LIBERTY AD CHRONOS study. This study met its primary and secondary endpoints, with patients receiving Dupixent with topical corticosteroids (TCS) achieving significantly improved measures of overall disease severity at 16 and 52 weeks, compared to TCS alone in adults with uncontrolled moderate-to-severe atopic dermatitis.

Phase 3 Study in Adolescent Patients. In the first quarter of 2017, a Phase 3 study in adolescent patients (12-17 years of age) with moderate-to-severe atopic dermatitis was initiated.

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

Asthma

Phase 3 Study. LIBERTY ASTHMA QUEST is a Phase 3 trial that evaluated dupilumab in adult and adolescent patients with uncontrolled persistent asthma. It is a global, placebo-controlled Phase 3 study that enrolled more than 1,900 patients with uncontrolled persistent asthma. This study included four study groups with patients treated with 200 mg every other week with a loading dose of 400 mg, 300 mg every other week with a loading dose of 600 mg, and two separate placebo groups. Patients were randomized in a 2:1 fashion to active drug versus placebo. The two primary endpoints of the study were the annualized rate of severe exacerbation events at 52 weeks and the absolute change from baseline in a standard measure of lung function known as pre-bronchodilator forced expiratory volume over one second (FEV_1) at 12 weeks (changes of 100 to 200 mL are considered clinically relevant). The pre-specified primary analysis included hierarchical evaluation of these endpoints in the overall population, in patients with 150 eosinophilic cells/microliter or greater, and in patients with 300 eosinophilic cells/microliter or greater. In the study, approximately 50% of patients had 300 eosinophilic cells/microliter or greater and approximately 70% of patients had 150 eosinophilic cells/microliter or greater. Higher eosinophil counts are generally thought to be associated with poorer asthma control and higher rates of exacerbations, as was observed in the placebo patients in this study.

In the third quarter of 2017, we and Sanofi announced that the Phase 3 LIBERTY ASTHMA QUEST study of dupilumab in a broad population of patients with uncontrolled, persistent asthma met its two primary endpoints. Dupilumab, when added to standard therapies, reduced severe asthma attacks (exacerbations) and improved lung function. At 52 weeks, in the 300 mg dose group, dupilumab reduced severe asthma attacks by 46% in the overall population, 60% in patients with 150 eosinophilic cells/microliter or greater, and 67% in patients with 300 eosinophilic cells/microliter or greater ($p<0.001$ for all groups). At 12 weeks, in the 300 mg dupilumab dose group, mean improvement in lung function over placebo as assessed by FEV_1 was 130 mL (9%) in the overall population, 150 mL (11%) in patients with 150 eosinophilic cells/microliter or greater, and 240 mL (18%) in patients with 300 eosinophilic cells/microliter or greater ($p<0.001$ for all groups).

In the LIBERTY ASTHMA QUEST study, the results for the 200 mg and 300 mg dupilumab dose groups were generally comparable on both exacerbations and FEV_1. The extent of patient response correlated with allergic or atopic status as reflected by blood eosinophils and other markers. Less activity was observed in patients with less than 150 eosinophilic cells/microliter. The overall rates of adverse events, deaths, infections, conjunctivitis, herpes, and discontinuations were comparable between the dupilumab and placebo groups. Injection site reactions were more common in the dupilumab groups occurring in 17% of dupilumab patients compared to 8% of placebo patients. All patients continued on a medium or high dose inhaled corticosteroid (ICS) and up to two additional controller medicines throughout the study. Eosinophil subgroups were classified based on baseline levels. Detailed results from this study will be submitted for presentation at a future medical congress.

In the fourth quarter of 2017, we and Sanofi announced that LIBERTY ASTHMA VENTURE, a randomized Phase 3 study examining the ability of dupilumab to reduce oral corticosteroid use in adults and adolescents with severe steroid-dependent asthma, met its primary endpoint and key secondary endpoints. The VENTURE study enrolled 210 patients (103 in the dupilumab group and 107 in the placebo group) with severe asthma and regular use of maintenance oral corticosteroids (OCS) in the six months prior to enrollment in the study. This Phase 3 study enrolled severe steroid-dependent asthma patients regardless of eosinophil levels or other biomarkers at baseline, and the results showed improvements compared to placebo on lung function and exacerbations across patient subgroups - those with baseline eosinophil counts above 300 cells/microliter, above 150 cells/microliter, and below 150 cells/microliter.

For the primary endpoint, at 24 weeks in the overall population, dupilumab added to standard therapies significantly reduced the use of maintenance OCS by 70% on average (median reduction of 100%) compared to 42% with placebo (median reduction of 50%) ($p<0.0001$). In prespecified analyses of patients with baseline eosinophil counts greater than or equal to 300 cells/microliter, adding dupilumab significantly reduced OCS use by 80% on average (median reduction of 100%) compared to 43% for placebo (median reduction of 50%) (nominal $p=0.0001$). At 24 weeks, despite the reduced use of OCS, patients treated with dupilumab had 59% fewer attacks (exacerbations) in the overall population ($p<0.0001$) and 71% fewer attacks in patients with eosinophil counts greater than or equal to 300 cells/microliter. Also at 24 weeks, compared to placebo, dupilumab improved lung function, as assessed by FEV_1 by 220 mL (15%) in the overall population ($p=0.0007$) and by 320 mL (25%) in patients with eosinophil counts greater than or equal to 300 cells/microliter (nominal $p=0.0049$).

The safety and tolerability profile of dupilumab in the LIBERTY ASTHMA VENTURE study was consistent with previous studies. There were more dupilumab-treated patients with injection site reactions (9% dupilumab vs. 4% placebo). There were more dupilumab-treated patients with an increase in eosinophil counts (14% dupilumab vs. 1% placebo), most of which were mild and the vast majority of which resolved. The overall rates of adverse events, including infections, conjunctivitis, and herpes, were comparable between the dupilumab and placebo groups. Patients with severe chronic asthma live with a profound decrease in their

lung function, approximately 52% of predicted normal for those in this study at baseline, which impacts their ability to breathe normally, and may lead to frequent exacerbations that require acute treatment and hospitalization. These problems occur even in patients who are treated with chronic OCS to manage their symptoms.

LIBERTY ASTHMA QUEST will serve as the second required pivotal efficacy study for the sBLA for asthma, since, based on discussions with the FDA, the Phase 2b study will also be considered a pivotal efficacy study. The results from the LIBERTY ASTHMA VENTURE study will also be included in the sBLA for asthma.

The TRAVERSE trial, a long-term safety extension study, is also included in the LIBERTY ASTHMA clinical development program.

Phase 3 Study in Pediatric Patients. In the second quarter of 2017, a Phase 3 study in pediatric patients (6-11 years of age) with uncontrolled persistent asthma was initiated.

Nasal Polyps

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

Eosinophilic Esophagitis

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

In the second quarter of 2017, we and Sanofi announced that a positive primary analysis from a Phase 2 proof-of-concept study of dupilumab in patients with active, moderate-to-severe EoE was completed. In the fourth quarter of 2017, we and Sanofi presented the results from this study at the World Congress of Gastroenterology. The study showed that patients who received dupilumab weekly reported a significant improvement in the ability to swallow versus placebo. The primary endpoint of the study was the change from baseline to week 10 in the Straumann Dysphagia Instrument (SDI) score, a patient-reported measure of swallowing difficulty on a 0-9 point scale, with 9 indicating more severe symptoms. A total of 47 patients were randomized into two treatment groups in this 12-week treatment study, and both groups had a mean baseline SDI score of 6.4. Patients received either dupilumab 300 mg weekly following a 600 mg loading dose or placebo. At week 10, patients who received dupilumab 300 mg weekly reported a significant improvement in the ability to swallow with a three point reduction in their SDI score (45% improvement) compared to 1.3 points (19% improvement) for those patients who received placebo ($p=0.0304$).

Secondary endpoints of the study included measures of the impact of dupilumab on endoscopic and histopathologic measures of disease severity, as well as symptoms. The results include:

- The mean change in the Eosinophilic Esophagitis Endoscopic Reference Score (EoE-EREFS) was significantly reduced by 1.9 points from baseline (48% improvement) in patients who received dupilumab weekly compared to 0.3 points (7% improvement) for those who received placebo at 12 weeks ($p=0.0006$). EoE-EREFS is a visual measure of disease severity (inflammation and fibrosis in the esophagus) on a 0-8 point scale, with 8 indicating more severe disease. The mean baseline score for the dupilumab group was 3.9 and for the placebo group was 4.3.
- The mean percent change in overall peak intraepithelial eosinophil count from baseline to 12 weeks was significantly reduced by 93% from baseline in patients who received dupilumab weekly compared to an increase of 14% in those who received placebo ($p<0.0001$).
- The mean percent change in a composite measure of symptoms and quality of life, as measured by Eosinophilic Esophagitis Symptom Activity Index (EEsAI), was numerically improved (although not statistically significant) by 35% in patients who received dupilumab weekly compared to an 11% improvement for those who received placebo at 10 weeks ($p=0.085$).

There were no new significant safety concerns in this trial. Higher rates of injection site reactions were observed on dupilumab versus placebo.

In the third quarter of 2017, the FDA granted orphan drug designation for the treatment of EoE.

Praluent for LDL cholesterol reduction

Overview

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol (LDL-C) through inhibition of HMG-CoA, an enzyme regulating the early and rate-limiting step in cholesterol biosynthesis that ultimately results in an increase in LDL receptors to increase the uptake of plasma LDL lipoproteins. Similar to statins, PCSK9 impacts the number of available LDL receptors and therefore plays a key role in modulating LDL-C levels in the body. PCSK9 is a secreted protein that binds to and induces the destruction of the LDL receptor, thereby interfering with cellular uptake and increasing circulating levels of LDL cholesterol. In a landmark study published in *The New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL-C, but also a significant reduction in the risk of coronary heart disease (CHD). We used our *VelocImmune* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called Praluent, which is intended to lower LDL cholesterol.

Clinical Program

Phase 3 ODYSSEY Program. The potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial, which is fully enrolled and is expected to be completed in 2017 (with data expected in early 2018). All patients who entered the ODYSSEY OUTCOMES trial had experienced a heart attack or unstable angina requiring hospitalization within the previous year before entering the trial, and experienced inadequately controlled LDL cholesterol despite receiving maximally-tolerated statins and potentially other lipid-lowering therapies. In 2016, an independent Data Monitoring Committee (DMC) of the ODYSSEY OUTCOMES study completed the first and second interim analyses. Based on the recommendation of the independent DMC, the ODYSSEY OUTCOMES trial continues as planned. Regeneron remains blinded to the actual results of the first and second interim analyses, and the DMC will continue to monitor the ongoing safety and efficacy of Praluent as planned.

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

In the second quarter of 2017, we and Sanofi presented positive results from two Phase 3b/4 studies (ODYSSEY-INSULIN and ODYSSEY-DYSLIPIDEMIA) which evaluated Praluent in patients with diabetes. Both studies found that a majority of patients reached their lipid goals with Praluent 75 mg administered every two weeks, with an overall safety profile comparable to the ODYSSEY Phase 3 program.

In the fourth quarter of 2017, a Phase 3 study in HoFH was initiated.

Kevzara (sarilumab; IL-6R Antibody) for inflammatory diseases

Overview

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

Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. SARIL-NIU-SATURN was a small Phase 2, randomized double-masked, placebo-controlled study (n=58) conducted to assess the effect of sarilumab on non-infectious uveitis of the posterior ocular segment. Based on the results of this study, no further development is currently planned in this indication.

Polyarticular-course Juvenile Idiopathic Arthritis (pcJIA)

Phase 2 pcJIA Study. A Phase 2 study of sarilumab in pcJIA was initiated in 2016.

Cemiplimab (REGN2810; PD-1 Antibody) for cancer

Overview

The PD-1/PD-L1 pathway has emerged as a critical regulator of effective immune responses to a variety of cancers, and a number of agents blocking either PD-1 or PD-L1 have been approved. Cemiplimab is a high-affinity anti-PD-1 human antibody that was generated using the *Velocimmune* platform. Cemiplimab is being developed to provide a foundational component for a planned, diverse immuno-oncology portfolio. Initial efforts for approval are expected to be as monotherapy in selected indications, and subsequent development is expected to be focused on combinations with other anti-cancer agents.

Clinical Program

Cemiplimab is in Phase 1 clinical development in a variety of malignancies as monotherapy or in combination with other antibodies or treatments. A pivotal Phase 2 study for the treatment of metastatic or locally advanced and unresectable CSCC was initiated in 2016. A Phase 3 study in first-line treatment for non-small cell lung cancer and a potentially pivotal Phase 2 study in BCC were initiated in the second quarter of 2017. A Phase 3 study in cervical cancer was initiated in the third quarter of 2017.

In June 2017, we and Sanofi announced positive preliminary results in patients with advanced CSCC. The data, pooled from two expansion cohorts of the cemiplimab Phase 1 trial, were presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. Treatment with cemiplimab led to an investigator-assessed overall response rate (ORR) of 46.2% and a disease control rate (DCR) of 69.2%. The median progression-free survival and overall survival were not reached at the data cutoff date with a median follow up of 6.9 months (range: 1.1 to 13.8 months; ongoing). One patient experienced progressive disease during treatment with cemiplimab after the initial response, and two patients were not evaluable due to death, which was considered unrelated to cemiplimab. The most common treatment-related adverse event of any grade was fatigue (23.1%). All grade 3 or higher adverse events occurred once and included arthralgia (3.8%), maculopapular rash (3.8%), asthenia (3.8%), aspartate aminotransferase (AST) elevation (3.8%), and alanine aminotransferase (ALT) elevation (3.8%). No apparent association between the objective response and level of PD-L1 (programmed death ligand 1) expression was found. These results are from 10 patients with distantly metastatic CSCC who were enrolled in one expansion cohort and 16 patients with inoperable (unresectable) locally or regionally advanced CSCC who were enrolled in a second expansion cohort.

In the third quarter of 2017, the FDA granted Breakthrough Therapy designation for the treatment of adults with metastatic CSCC and adults with locally advanced and unresectable CSCC.

In the second quarter of 2017, we and Inovio Pharmaceuticals, Inc. entered into a clinical and supply agreement for a Phase 1b/2a immuno-oncology trial. The study will be conducted by Inovio in patients with newly-diagnosed glioblastoma multiforme (GBM) and will evaluate cemiplimab in combination with Inovio's INO-5401 T cell activating immunotherapy encoding multiple antigens and INO-9012, an immune activator encoding IL-12. Also in the second quarter of 2017, we and SillaJen, Inc. entered into a clinical and supply agreement for a Phase 1b dose-escalation study in renal cell carcinoma (RCC), or kidney cancer. The study will evaluate cemiplimab in combination with SillaJen's oncolytic vaccinia virus, Pexa-Vec, in patients with previously treated metastatic or unresectable renal cell carcinoma.

Fasinumab (REGN475; NGF Antibody) for pain due to osteoarthritis and chronic low back pain

Overview

Pain is a frequent reason for physician visits, a common reason for taking prescription medications (including opioids), and a major cause of work disability and impaired quality of life. Targeting NGF is a potential non-opioid advance in pain management. NGF expression is elevated in many acute and chronic painful conditions and NGF blockade has demonstrated efficacy in clinical trials. Fasinumab is a fully human monoclonal antibody to NGF, generated using our *VelocImmune* technology.

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

Osteoarthritis

Phase 2/3 Study. In the second quarter of 2016, we announced positive, 16-week top-line data from a Phase 2/3 study in patients with moderate-to-severe osteoarthritis pain of the hip or knee who have a history of inadequate pain relief or intolerance to current analgesic therapies. In the fourth quarter of 2016, we and Teva announced that at the 36-week analysis of the Phase 2/3 clinical study in patients with moderate-to-severe osteoarthritis pain of the hip or knee, the incidence of adjudicated arthropathies was found to be potentially dose-dependent, with a higher rate of patients experiencing arthropathies in the higher dose groups (12% (9mg), 7% (6mg), 5% (3mg), 2% (1mg), and 1% (placebo)). In the ongoing fasinumab osteoarthritis pivotal Phase 3 program (further described below), we and our collaborators are planning to advance only the lower doses from the Phase 2/3 study.

Phase 3 Study. A Phase 3 long-term safety study in patients with pain due to osteoarthritis of the knee or hip was initiated in 2016. A Phase 3 efficacy study in patients with pain due to osteoarthritis of the knee or hip was initiated in the second quarter of 2017. A Phase 3 efficacy study of fasinumab compared to placebo or naproxen in patients with pain due to osteoarthritis of the knee or hip was initiated in the third quarter of 2017.

Chronic Low Back Pain

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

We and Teva plan to initiate a pivotal Phase 3 program in chronic low back pain.

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, and infectious diseases.

In 2015, we and BARDA of the HHS entered into an agreement to develop, test, and manufacture a monoclonal antibody therapy (REGN3470-3471-3479) for the treatment of Ebola virus infection. Under the terms of the agreement, HHS provides funding to support our preclinical development, antibody manufacturing, and for a Phase 1 study in healthy volunteers, and has the option to provide additional funding for further manufacturing and development studies. In September 2017, we and BARDA entered into an additional agreement whereby HHS provides additional funding for the continued development of REGN3470-3471-3479, a potential BLA filing, and initial procurement of the therapy for national security preparedness. In addition, in 2016, we and BARDA entered into an agreement whereby HHS will provide certain funding to manufacture and study two antibody therapies for the potential treatment of Middle East Respiratory Syndrome (MERS).

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

In the first quarter of 2017, the Regeneron Genetics Center (RGC) entered into an agreement with U.K. Biobank and GlaxoSmithKline (GSK) to generate genetic sequence data from the volunteer participants in the U.K. Biobank resource. RGC ultimately plans to generate genetic sequence data from the 500,000 volunteer participants in the U.K. Biobank resource, and RGC and GSK have committed an initial investment to enable the sequencing of 50,000 samples. The sequencing of U.K. Biobank's samples will be performed at the RGC facility. These sequence data will be incorporated back into U.K. Biobank's resource following a standard exclusivity period for GSK and Regeneron and made openly available to the broader scientific community.

License Agreements

In September 2017, we entered into a license agreement with a third party, which grants the third party the right to develop and commercialize new indications for ARCALYST in certain jurisdictions, including the United States. We currently maintain exclusive rights to ARCALYST in the United States for existing indications, and are entitled to all profits from such sales. Commencing with the receipt of marketing approval by the third party for the first new indication in the United States, we will grant commercial rights to ARCALYST for our existing indications to the third party.

Collaboration Agreements

Collaborations with Sanofi

***Antibodies*.** Since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement (Antibody Discovery Agreement) and a License and Collaboration Agreement (each as amended), collectively referred to as the Antibody Collaboration. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi is responsible for funding up to $130.0 million of our antibody discovery activities in 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the Antibody Discovery Agreement, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug application (IND) or its equivalent, toxicology studies, and manufacture

of preclinical and clinical supplies. Our Antibody Discovery Agreement with Sanofi will end on December 31, 2017 without any extension. Praluent (anti-PCSK9), Dupixent (anti-IL-4R), Kevzara (anti-IL-6R), cemiplimab (anti-PD-1), REGN3500 (anti-IL-33), and REGN3767 (anti-LAG-3) were discovered and initially developed under the Antibody Discovery Agreement. Praluent, Dupixent, Kevzara, and REGN3500 will continue to be developed, and commercialized as applicable, with Sanofi under the Antibody License and Collaboration Agreement. Cemiplimab and REGN3767 will continue to be developed with Sanofi under the immuno-oncology collaboration. Upon expiration of the Antibody Discovery Agreement, we have the right to develop or continue to develop other product candidates discovered under this agreement independently or with other collaborators.

For each drug candidate identified through discovery research under the Antibody Discovery Agreement, Sanofi has the option to license rights to the candidate under the License and Collaboration Agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs as they are incurred by us, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-promote such products on a country-by-country basis. We have exercised our option to co-promote Dupixent, Praluent, and Kevzara in the United States. We have not exercised any of our options to co-promote these antibodies outside the United States; however, we retain the right to do so at a future date subject to the terms of the collaboration agreement. We and Sanofi will equally share profits and losses from sales within the United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and share losses outside the United States at 55% (Sanofi)/45% (us). In addition to profit sharing, we are entitled to receive up to $250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed $1.0 billion on a rolling 12-month basis.

Immuno-Oncology. In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million (IO Discovery Budget) to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits (up to $200.0 million for 2017). The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of IND Applications, and clinical development through proof-of-concept. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized IO Collaboration products to the extent they are sufficient for this purpose. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement (as further described below).

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future IO Collaboration profits to the extent they are sufficient for this purpose. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each

party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in profits and losses in connection with the commercialization of collaboration products.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (cemiplimab). We have principal control over the development of cemiplimab, and the parties share equally, on an ongoing basis, development expenses for cemiplimab up to a total of $650.0 million. We will lead commercialization activities in the United States, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. Sanofi has exercised its option to co-promote cemiplimab in the United States. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including cemiplimab), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

Collaborations with Bayer

EYLEA outside the United States. Since October 2006, we and Bayer have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer collaborate on, and share the costs of, the development of EYLEA. Bayer markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, we are entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits (including payments to us based on sales in Japan). The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer at a faster rate. As a result, we expect that a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer for this repayment obligation.

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

Ang2 antibody outside the United States. In March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including REGN910-3 (nesvacumab in combination with aflibercept), for the treatment of ocular diseases or disorders. Nesvacumab/aflibercept, a combination product candidate comprised of an antibody to Ang2 co-formulated with aflibercept, is being developed under the agreement. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to us and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. We are also entitled to receive up to an aggregate of $80.0 million in development milestone payments from Bayer. Bayer will share profits and losses from sales outside the United States equally with us, and is responsible for certain royalties payable to Sanofi on sales of the product outside of the United States. Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales.

Collaboration with Mitsubishi Tanabe Pharma

Fasinumab. In September 2015, we entered into a collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) providing MTPC with development and commercial rights to fasinumab in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the MTPC Territories). In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment in 2015, and in 2016, MTPC made additional payments totaling $60.0 million to us. In the second quarter of 2017, we earned a $30.0 million development milestone from MTPC, and we are entitled to receive up to an aggregate of $125.0 million in additional development milestone and other contingent payments.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200.0 million.

Collaboration with Teva

***Fasinumab*.** In September 2016, we entered into a collaboration agreement with Teva to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with MTPC (as described above). In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment in 2016. We will lead global development activities, and the parties will share equally, on an ongoing basis, development costs under a global development plan. In the second quarter of 2017, we earned a $25.0 million development milestone from Teva, and we are entitled to receive up to an aggregate of $435.0 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).

General

Developing and commercializing new medicines entails significant risk and expense. Before significant revenues from the commercialization of our antibody candidates or new indications for our marketed products can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of Dupixent, Praluent, and Kevzara, as well as preparation for potential commercialization of other indications of dupilumab. 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.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2017 to date were, and plans for the next twelve months are, as follows:

Trap-based Clinical Program:

	2017 Events to Date	2017-2018 Plans (next 12 months)
EYLEA	Ÿ Bayer received regulatory approval for EYLEA for various indications and continued to pursue regulatory applications for marketing approval in additional countries Ÿ Completed patient enrollment in Phase 3 study for the treatment of NPDR in patients without DME	Ÿ Bayer to submit for additional regulatory approvals outside the United States for various indications Ÿ Regulatory agency decisions on applications outside the United States for various indications Ÿ File sBLA with FDA for every 12-week dosing interval in wet AMD Ÿ Report data from Phase 3 study for the treatment of NPDR in patients without DME Ÿ Submit sBLA for NPDR in patients without DME Ÿ Report results from Phase 2 co-formulation studies of nesvacumab/aflibercept

Antibody-based Clinical Programs:

	2017 Events to Date	2017-2018 Plans (next 12 months)
Dupixent (dupilumab; IL-4R Antibody)	Ÿ Presented detailed results from one-year Phase 3 CHRONOS study at the Annual Meeting of the American Academy of Dermatology Ÿ FDA approved Dupixent for the treatment of adults with moderate-to-severe atopic dermatitis Ÿ Initiated Phase 3 study in adolescent patients (12-17 years of age) with atopic dermatitis Ÿ Regulatory applications submitted for atopic dermatitis in Japan and various other jurisdictions outside the United States Ÿ Reported positive results from the LIBERTY AD CAFÉ study in atopic dermatitis Ÿ European Commission granted marketing approval for Dupixent for the treatment of adults with moderate-to-severe atopic dermatitis Ÿ Initiated Phase 3 study in pediatric patients (6-11 years of age) with asthma Ÿ Reported positive top-line results from Phase 3 LIBERTY ASTHMA QUEST trial Ÿ Reported positive top-line results from Phase 3 LIBERTY ASTHMA VENTURE study Ÿ Reported positive results from Phase 2 study in EoE Ÿ FDA granted orphan drug designation for the treatment of EoE Ÿ Completed patient enrollment in Phase 3 study in nasal polyps	Ÿ Submit for additional regulatory approvals in atopic dermatitis outside the United States Ÿ Regulatory agency decisions on atopic dermatitis applications outside the United States Ÿ Initiate Phase 3 studies in younger pediatric patients in atopic dermatitis Ÿ Submit sBLA for asthma in adult/adolescent patients Ÿ Submit for EU regulatory approval in asthma in adult/adolescent patients Ÿ Initiate Phase 3 study in EoE Ÿ Initiate Phase 2 study in peanut allergy
Praluent (PCSK9 Antibody)	Ÿ Permanent injunction barring commercialization of Praluent in the United States suspended on February 8, 2017 and vacated on October 5, 2017 Ÿ FDA approved sBLA for monthly dosing regimen Ÿ FDA granted orphan drug designation for treatment of HoFH Ÿ Reported positive results from two Phase 3b/4 trials in patients with diabetes Ÿ ODYSSEY study data presented at the European Society of Cardiology (ESC) Congress Ÿ Initiated Phase 3 study in HoFH	Ÿ Complete and report results from ODYSSEY OUTCOMES study Ÿ Submit for additional regulatory approvals outside the United States Ÿ Regulatory agency decisions on applications outside the United States Ÿ File sBLA with FDA for use with apheresis Ÿ Initiate Phase 3 pediatric studies in HoFH and HeFH

Antibody-based Clinical Programs (continued):

	2017 Events to Date	2017-2018 Plans (next 12 months)
Kevzara (sarilumab; IL-6R Antibody)	Ÿ Regulatory applications submitted in various jurisdictions outside the United States Ÿ Health Canada approved Kevzara for the treatment of adult patients with RA Ÿ Resubmitted BLA and FDA accepted for review Ÿ FDA approved Kevzara for the treatment of adult patients with RA Ÿ European Commission granted marketing authorization for Kevzara for the treatment of adult patients with RA	Ÿ Submit for additional regulatory approvals outside of the United States Ÿ Regulatory agency decisions on applications outside the United States Ÿ Continue patient enrollment in Phase 2 study in pcJIA
Suptavumab (RSV-F Antibody)	Ÿ Completed patient enrollment in Phase 3 study Ÿ Reported results from Phase 3 study, and discontinued further clinical development	
Cemiplimab (REGN2810; PD-1 Antibody)	Ÿ Continued patient enrollment in Phase 1 and Phase 2 studies Ÿ Reported positive preliminary results from Phase 1 trial in patients with advanced CSCC Ÿ FDA granted Breakthrough Therapy designation for the treatment of adults with metastatic CSCC and adults with locally advanced and unresectable CSCC Ÿ Initiated Phase 3 study in first-line treatment for non-small cell lung cancer Ÿ Initiated potentially pivotal Phase 2 study in BCC Ÿ Initiated Phase 3 study in cervical cancer	Ÿ Report interim data from pivotal Phase 2 CSCC study Ÿ Submit BLA for CSCC Ÿ Submit for regulatory approval in CSCC in the EU Ÿ Initiate additional studies in non-small cell lung cancer Ÿ Continue patient enrollment in various studies
Fasinumab (NGF Antibody)	Ÿ Continued patient enrollment in Phase 3 long-term safety study in osteoarthritis Ÿ Initiated Phase 3 efficacy study in osteoarthritis	Ÿ Continue patient enrollment in Phase 3 studies in osteoarthritis Ÿ Initiate additional Phase 3 studies in osteoarthritis Ÿ Initiate Phase 3 program in chronic low back pain
Evinacumab (Angptl-3 Antibody)	Ÿ FDA granted Breakthrough Therapy designation for the treatment of hypercholesterolemia in patients with HoFH Ÿ Reported positive Phase 2 results at medical conferences Ÿ Data and analysis from genetics, preclinical, and clinical study published in the *New England Journal of Medicine*	Ÿ Initiate Phase 3 study in HoFH Ÿ Initiate Phase 2 study in severe hypertriglyceridemia Ÿ Initiate Phase 2 study in refractory hypercholesterolemia (both HeFH and non-FH)
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	Ÿ Completed patient enrollment in Phase 2 ONYX study in wet AMD	Ÿ Report results from ONYX and RUBY Phase 2 studies
Trevogrumab (GDF8 Antibody)	Ÿ Initiated Phase 1 combination therapy study with REGN2477 Ÿ Completed patient enrollment in Phase 1 combination therapy study	Ÿ Complete Phase 1 combination study

Antibody-based Clinical Programs (continued):

	2017 Events to Date	2017-2018 Plans (next 12 months)
REGN1908-1909 (Feld1 Antibody)		Ÿ Continue early stage development
REGN1979 (CD20 and CD3 Antibody)	Ÿ Continued patient enrollment in Phase 1 study Ÿ FDA granted orphan drug designation in diffuse large B-cell lymphoma	Ÿ Continue patient enrollment in Phase 1 study
REGN3470-3471-3479 (Multi-antibody therapy to Ebola virus)	Ÿ Completed Phase 1 study in healthy volunteers	Ÿ Initiate additional healthy volunteer study
REGN2477 (Activin A Antibody)	Ÿ FDA granted orphan drug designation for the treatment of FOP Ÿ FDA granted Fast Track designation for the prevention and treatment of heterotopic ossification in patients with FOP	Ÿ Initiate Phase 2 study in patients with FOP
REGN3500 (IL-33 Antibody)	Ÿ Initiated Phase 1 studies in patients with asthma Ÿ Completed Phase 1 study in healthy volunteers	Ÿ Initiate Phase 2 study
REGN3767 (LAG-3 Antibody)	Ÿ Continued patient enrollment in Phase 1 study	Ÿ Continue patient enrollment in Phase 1 study
REGN3918 (C5 Antibody)	Ÿ Initiated Phase 1 study in healthy volunteers	Ÿ Complete Phase 1 study in healthy volunteers

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.

Results of Operations

Three and Nine Months Ended September 30, 2017 and 2016

Net Income

Net Income (In millions)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Increase (Decrease)	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Increase (Decrease)
Revenues	$ 1,500.7	$ 1,220.1	$ 280.6	$ 4,289.8	$ 3,633.6	$ 656.2
Operating expenses	(940.7)	(857.3)	(83.4)	(2,749.0)	(2,649.9)	(99.1)
Other (expense) income, net	5.7	3.1	2.6	(17.0)	4.6	(21.6)
Income before income taxes	565.7	365.9	199.8	1,523.8	988.3	535.5
Income tax expense	(177.3)	(101.1)	(76.2)	(498.8)	(345.9)	(152.9)
Net income	$ 388.4	$ 264.8	$ 123.6	$ 1,025.0	$ 642.4	$ 382.6
Net income per share - diluted	$ 3.32	$ 2.27	$ 1.05	$ 8.84	$ 5.51	$ 3.33

Revenues

Revenues (In millions)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Increase (Decrease)	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Increase (Decrease)
Net product sales in the United States:						
EYLEA	$ 953.3	$ 853.6	$ 99.7	$ 2,727.1	$ 2,465.4	$ 261.7
ARCALYST	4.1	3.9	0.2	12.6	10.5	2.1
Sanofi and Bayer collaboration revenue:						
Sanofi	245.2	144.4	100.8	677.7	527.5	150.2
Bayer	236.6	191.3	45.3	640.9	562.8	78.1
Other revenue	61.5	26.9	34.6	231.5	67.4	164.1
Total revenues	$ 1,500.7	$ 1,220.1	$ 280.6	$ 4,289.8	$ 3,633.6	$ 656.2

Net Product Sales

Net product sales of EYLEA in the United States increased for the three and nine months ended September 30, 2017, compared to the same periods in 2016, due to higher sales volume, partly offset by an increase in sales-related deductions primarily due to payer sales mix and new rebate programs.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions and credits/payments for sales-related deductions.

(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2016	$ 12.7	$ 29.5	$ 3.6	$ 45.8
Provisions	38.9	41.2	9.5	89.6
Credits/payments	(28.5)	(42.3)	(8.6)	(79.4)
Balance as of March 31, 2017	23.1	28.4	4.5	56.0
Provisions	39.4	48.8	11.1	99.3
Credits/payments	(39.4)	(48.2)	(12.7)	(100.3)
Balance as of June 30, 2017	23.1	29.0	2.9	55.0
Provisions	43.3	50.9	12.9	107.1
Credits/payments	(40.9)	(45.8)	(0.1)	(86.8)
Balance as of September 30, 2017	$ 25.5	$ 34.1	$ 15.7	$ 75.3
Balance as of December 31, 2015	$ 6.4	$ 48.3	$ 0.5	$ 55.2
Provisions	18.9	35.8	2.9	57.6
Credits/payments	(17.5)	(50.4)	(2.5)	(70.4)
Balance as of March 31, 2016	7.8	33.7	0.9	42.4
Provisions	22.4	38.5	9.4	70.3
Credits/payments	(18.6)	(44.1)	(9.2)	(71.9)
Balance as of June 30, 2016	11.6	28.1	1.1	40.8
Provisions	22.2	39.5	10.5	72.2
Credits/payments	(26.4)	(41.0)	(7.8)	(75.2)
Balance as of September 30, 2016	$ 7.4	$ 26.6	$ 3.8	$ 37.8

Sanofi Collaboration Revenue

Sanofi Collaboration Revenue	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
(In millions)	**2017**	**2016**	**2017**	**2016**
Antibody:				
Reimbursement of Regeneron research and development expenses - Discovery Agreement	$ 37.9	$ 24.4	$ 130.0	$ 130.0
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	90.6	107.0	291.1	339.2
Reimbursement of Regeneron commercialization-related expenses	90.3	64.4	251.0	214.0
Regeneron's share of losses in connection with commercialization of antibodies	(98.3)	(112.0)	(329.0)	(333.5)
Other	41.9	4.4	84.3	19.9
Total Antibody	162.4	88.2	427.4	369.6
Immuno-oncology:				
Reimbursement of Regeneron research and development expenses - Discovery Agreement	33.9	20.6	111.1	63.3
Reimbursement of Regeneron research and development expenses - License and Collaboration Agreement	27.8	15.6	77.3	34.6
Other	21.1	20.0	61.9	60.0
Total Immuno-oncology	82.8	56.2	250.3	157.9
Total Sanofi collaboration revenue	$ 245.2	$ 144.4	$ 677.7	$ 527.5

The lower reimbursement of antibody research and development costs under our License and Collaboration Agreement during the three and nine months ended September 30, 2017, compared to the same periods in 2016, was primarily due to decreased reimbursement levels for Dupixent (dupilumab) subsequent to the receipt of the first positive Phase 3 trial results, and U.S. regulatory approval, in accordance with the terms of our collaboration agreement.

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

During the three and nine months ended September 30, 2017 and 2016, we and Sanofi shared commercial expenses related to Praluent, Kevzara, and Dupixent in accordance with the companies' License and Collaboration Agreement. As such, during the same periods in which we recorded reimbursements from Sanofi related to our commercialization expenses, we also recorded our share of losses in connection with the companies commercializing Praluent, Kevzara, and Dupixent within Sanofi collaboration revenue. During the three and nine months ended September 30, 2017, compared to the same periods in 2016, Sanofi antibody collaboration revenues were positively impacted by higher sales of collaboration antibody products (see table below) and a decrease in the collaborations' Praluent commercialization expenses, which were partially offset by an increase in the collaborations' Dupixent and Kevzara commercialization expenses. Sanofi provides us with an estimate of our share of the losses from commercialization of antibodies for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. Sanofi records product sales for commercialized products.

The following table summarizes global net product sales recorded by Sanofi:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2017**	**2016**	**2017**	**2016**
Praluent in the United States	$ 31.8	$ 31.6	$ 89.8	$ 61.9
Praluent outside of the United States	17.6	6.6	41.6	13.8
Praluent global	49.4	38.2	131.4	75.7
Dupixent	88.9	—	117.6	—
Kevzara	3.0	—	3.8	—

In March 2017, the FDA approved Dupixent for the treatment of adult patients with moderate-to-severe atopic dermatitis, and in September 2017, the European Commission granted marketing authorization for Dupixent for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. In May 2017, the FDA approved Kevzara for the treatment of rheumatoid arthritis in adult patients, and in June 2017, the European Commission granted marketing authorization for Kevzara for the treatment of rheumatoid arthritis in adult patients.

During the three and nine months ended September 30, 2017, other Sanofi antibody revenue included (i) reimbursements by Sanofi in connection with validating our Limerick commercial manufacturing facilities as required under the terms of our collaboration agreement and (ii) an acceleration of the recognition of deferred revenue from an $85.0 million up-front payment and other payments in connection with Sanofi's decision to end our Antibody Discovery Agreement on December 31, 2017 without any extension.

Sanofi's reimbursement of immuno-oncology research and development costs under our IO Discovery Agreement increased in the third quarter and first nine months of 2017, compared to the same periods in 2016, primarily due to an increase in pre-clinical research activities for additional product candidates. Sanofi's reimbursement of immuno-oncology research and development costs under our IO License and Collaboration Agreement increased in the third quarter and first nine months of 2017, compared to the same periods in 2016, as we advanced the cemiplimab clinical program into late-stage clinical development.

Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in 2015 in connection with the execution of the IO Collaboration agreements.

Bayer Collaboration Revenue

Bayer Collaboration Revenue	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	**2017**	**2016**	**2017**	**2016**
EYLEA:				
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 205.4	$ 170.9	$ 571.1	$ 484.2
Reimbursement of Regeneron EYLEA development expenses	6.1	2.2	10.8	7.2
Other	15.7	6.1	36.9	45.9
Total EYLEA	227.2	179.2	618.8	537.3
Ang2 antibody and PDGFR-beta antibody:				
Reimbursement of development expenses	7.3	7.4	15.6	14.2
Other	2.1	4.7	6.5	11.3
Total Ang2 antibody and PDGFR-beta antibody	9.4	12.1	22.1	25.5
Total Bayer collaboration revenue	$ 236.6	$ 191.3	$ 640.9	$ 562.8

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

Regeneron's Net Profit from EYLEA Sales Outside the United States	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2017	2016	2017	2016
Net product sales outside the United States	$ 563.7	$ 470.8	$ 1,590.0	$ 1,375.9
Regeneron's share of collaboration profit from sales outside the United States	218.5	184.4	611.7	524.8
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(13.1)	(13.5)	(40.6)	(40.6)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 205.4	$ 170.9	$ 571.1	$ 484.2

Bayer records revenue from sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profit, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary.

We discontinued clinical development of rinucumab/aflibercept in the first quarter of 2017. In March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to us, which was recorded as deferred revenue and is being recognized as revenue over the related performance period. Bayer is also obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States.

Other Revenue

Other Revenue	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions)	2017	2016	2017	2016
Teva collaboration revenue:				
Reimbursement of Regeneron research and development expenses	$ 28.5	$ 3.1	$ 82.1	$ 3.1
Substantive development milestone	—	—	25.0	—
Other	11.7	2.1	33.9	2.1
Total Teva collaboration revenue	40.2	5.2	141.0	5.2
Other revenue	21.3	$ 21.7	90.5	62.2
Total other revenue	$ 61.5	$ 26.9	$ 231.5	$ 67.4

In September 2016, we and Teva entered into a collaboration agreement to develop and commercialize fasinumab. Other Teva collaboration revenue includes recognition of a portion of deferred revenue from a $250.0 million up-front payment. In the second quarter of 2017, we earned, and recognized as revenue, development milestones of $25.0 million and $30.0 million from Teva and MTPC, respectively. The revenue recognized in connection with the MTPC milestone is included in Other revenue in the table above.

Expenses

(In millions)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Increase (Decrease)	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Increase (Decrease)
Research and development	$ 529.7	$ 543.0	$ (13.3)	$ 1,547.2	$ 1,573.1	$ (25.9)
Selling, general, and administrative	306.8	270.0	36.8	910.5	851.8	58.7
Cost of goods sold	46.4	30.0	16.4	149.8	150.1	(0.3)
Cost of collaboration and contract manufacturing	57.8	14.3	43.5	141.5	74.9	66.6
Total operating expenses	$ 940.7	$ 857.3	$ 83.4	$ 2,749.0	$ 2,649.9	$ 99.1
Average headcount	5,875	5,127	748	5,653	4,786	867

Our average headcount in 2017 increased compared to 2016 principally in connection with expanding our manufacturing activities.

Operating expenses included a total of $125.1 million in the third quarter and $380.1 million in the first nine months of 2017, respectively, and $131.4 million in the third quarter and $405.3 million in the first nine months of 2016, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense).

Research and Development Expenses

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

Research and Development Expenses (In millions)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016*	Increase (Decrease)	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016*	Increase (Decrease)
Direct research and development expenses:						
Dupilumab	$ 50.0	$ 54.2	$ (4.2)	$ 150.0	$ 171.1	$ (21.1)
Cemiplimab	33.7	11.0	22.7	78.3	27.3	51.0
Fasinumab	39.1	29.4	9.7	112.0	76.9	35.1
Praluent	21.2	21.5	(0.3)	61.1	61.3	(0.2)
Suptavumab	17.0	8.4	8.6	31.4	18.4	13.0
Sarilumab	2.4	3.0	(0.6)	7.6	16.7	(9.1)
Other product candidates in clinical development and other research programs	55.2	61.1	(5.9)	168.4	189.4	(21.0)
Total direct research and development expenses	218.6	188.6	30.0	608.8	561.1	47.7
Indirect research and development expenses:						
Payroll and benefits	145.3	142.5	2.8	438.5	421.9	16.6
Clinical manufacturing costs	97.7	122.7	(25.0)	300.9	309.6	(8.7)
Research, licensing, and other development costs	17.1	40.6	(23.5)	47.1	139.6	(92.5)
Occupancy and other operating costs	51.0	48.6	2.4	151.9	140.9	11.0
Total indirect research and development expenses	311.1	354.4	(43.3)	938.4	1,012.0	(73.6)
Total research and development expenses	$ 529.7	$ 543.0	$ (13.3)	$ 1,547.2	$ 1,573.1	$ (25.9)

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

Direct research and development expenses increased for cemiplimab and fasinumab in the third quarter and first nine months of 2017, compared to the same periods in 2016, primarily due to continued enrollment in clinical studies and the initiation of additional clinical studies. Direct research and development expenses decreased for dupilumab in the first nine months of 2017, compared to the same period in 2016, as some later-stage clinical studies had been completed. Clinical manufacturing costs decreased in the third quarter of 2017, compared to the same period in 2016, primarily due to a higher proportion of commercial manufacturing at our facilities. Research, licensing, and other development costs in 2016 included the $75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia and the $25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet. Research and development expenses included Non-Cash Compensation Expense of $70.1 million and $213.2 million in the third quarter and first nine months of 2017, respectively, and $80.6 million and $238.0 million in the third quarter and first nine months of 2016, respectively.

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

(with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product.

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

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

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased for the three months ended September 30, 2017, compared to the same period in 2016, primarily due to higher headcount and headcount-related costs to support the launches of Dupixent and Kevzara and an increase in commercialization-related expenses associated with EYLEA and Dupixent. Selling, general, and administrative expenses increased for the nine months ended September 30, 2017, compared to the same period in 2016, primarily due to higher headcount and headcount-related costs to support the launches of Dupixent and Kevzara and an increase in commercialization-related expenses associated with EYLEA, Dupixent, and Kevzara, partly offset by lower commercialization-related expenses associated with Praluent. Selling, general, and administrative expenses included Non-Cash Compensation Expense of $47.7 million and $146.2 million in the third quarter and first nine months of 2017, respectively, and $49.4 million and $157.2 million in the third quarter and first nine months of 2016, respectively.

Cost of Goods Sold

Cost of goods sold increased for the three and nine months ended September 30, 2017, compared to the same periods in 2016, principally due to an increase in start-up costs for our Limerick manufacturing facility. For the nine months ended September 30, 2017, this increase was offset due to the fact that, effective May 2016, we are no longer obligated to pay royalties to Genentech based on U.S. sales of EYLEA.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased for the three months ended September 30, 2017, compared to the same period in 2016, primarily due to costs we incurred in connection with validating our Limerick manufacturing commercial facility in connection with our collaboration with Sanofi. Cost of collaboration and contract manufacturing increased for the nine months ended September 30, 2017, compared to the same period in 2016, primarily due to costs we incurred in connection with validating our Limerick manufacturing commercial facility related to products that are in collaboration with Sanofi, partly offset by the fact that the first nine months of 2016 included royalties payable to Genentech based on sales of EYLEA outside the United States (which ended in May 2016). Cost of collaboration and contract manufacturing was also adversely impacted by inventory write-offs and reserves totaling $50.6 million in the first nine months of 2017 primarily related to product that no longer met quality specifications, compared to $6.8 million in the first nine months of 2016.

Other Income and Expense

Other expenses in the first nine months of 2017 included the recognition of a $30.1 million loss on debt extinguishment related to the 2017 Tarrytown lease transaction. See Note 10 to our Condensed Consolidated Financial Statements.

Income Taxes

(In millions)	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Income tax expense	$ 177.3	$ 101.1	$ 498.8	$ 345.9
Effective tax rate	31.3%	27.6%	32.7%	35.0%

The effective tax rate for the three and nine months ended September 30, 2017 and 2016 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for increased research activities, offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. Our effective tax rate for the three months ended September 30, 2016 was also positively impacted by changes to tax reserves.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	September 30, 2017	December 31, 2016	Increase (Decrease)
Financial assets:			
Cash and cash equivalents	$ 792.1	$ 535.2	$ 256.9
Marketable securities - current	586.9	503.5	83.4
Marketable securities - non-current	1,327.3	864.3	463.0
	$ 2,706.3	$ 1,903.0	$ 803.3
Working capital:			
Current assets	$ 4,135.7	$ 3,180.2	$ 955.5
Current liabilities	1,138.6	1,241.5	(102.9)
	$ 2,997.1	$ 1,938.7	$ 1,058.4

Additionally, as of September 30, 2017, we 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 Nine Months Ended September 30, 2017 and 2016

(In millions)	September 30, 2017	September 30, 2016	Increase (Decrease)
Cash flows provided by (used in) operating activities	$ 740.2	$ 1,095.5	$ (355.3)
Cash flows provided by (used in) investing activities	(669.4)	(775.5)	106.1
Cash flows provided by (used in) financing activities	186.1	(208.7)	394.8

Cash Flows from Operating Activities

Our net income of $1,025.0 million in the first nine months of 2017 included Non-cash Compensation Expense of $380.1 million. Deferred tax assets as of September 30, 2017 increased by $108.2 million, compared to December 31, 2016, primarily due to Non-cash Compensation Expense. Sanofi, Bayer, and trade accounts receivable increased by $359.8 million as of September 30, 2017, compared to December 31, 2016, primarily due to higher EYLEA sales and higher production of commercial inventory in connection with our Sanofi collaboration.

Our net income of $642.4 million in the first nine months of 2016 included Non-cash Compensation Expense of $405.3 million. Deferred tax assets as of September 30, 2016 increased by $190.3 million, compared to December 31, 2015, primarily due to an increase in Non-cash Compensation Expense, the tax basis of intangible assets, and deferred revenue. Deferred revenue increased by $282.2 million as of September 30, 2016, compared to December 31, 2015, primarily due to $250.0 million and $60.0 million of payments received in the first nine months of 2016 from Teva and Mitsubishi, respectively, in connection with our fasinumab collaborations, and the $50.0 million up-front payment from Bayer in connection with the companies' Ang2 collaboration, partly offset by the amortization of these 2016 payments and up-front payments from Sanofi. Accounts payable, accrued expenses, and other liabilities increased by $107.4 million as of September 30, 2016, compared to December 31, 2015, primarily due to higher tax-related liabilities, partly offset by lower royalties payable since our obligation to pay Genentech based on sales of EYLEA ended in May 2016.

Cash Flows from Investing Activities

Capital expenditures were $165.0 million and $361.5 million in the first nine months of 2017 and 2016, respectively. Capital expenditures in the first nine months of 2017 primarily included costs in connection with renovations and additions to certain buildings at our Rensselaer, New York and Limerick, Ireland manufacturing facilities, as well as, to a lesser extent, at our Tarrytown, New York laboratory and office facilities. Capital expenditures in the first nine months of 2016 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility, tenant improvement and associated costs at our leased Tarrytown, New York facilities, renovations to certain areas of our Rensselaer, New York manufacturing facilities, the purchase of an office building near our Rensselaer manufacturing facilities, and purchases of equipment. Capital expenditures decreased in the first nine months of 2017, compared to the first nine months of 2016, in part due to less capital expenditures in connection with renovations at our Limerick, Ireland manufacturing facility as by the end of 2016 a substantial portion of the initial build-out of the plant had been completed. We expect to incur capital expenditures of approximately $100 million to $120 million during the fourth quarter of 2017.

Cash Flows from Financing Activities

In the first nine months of 2017, proceeds in connection with capital and facility lease obligations relate to our receipt of $57.0 million in connection with the March 2017 lease transaction as described below under "Tarrytown, New York Leases". In the first nine months of 2016, we paid an aggregate amount of $242.1 million to warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. No warrants remained outstanding as of December 31, 2016.

Credit Facility

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a $750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of September 30, 2017.

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 September 30, 2017.

Tarrytown, New York Leases

We lease laboratory and office facilities in Tarrytown, New York. On December 30, 2016, we entered into a Purchase Agreement with BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC (collectively, BMR), pursuant to which we agreed to purchase BMR's Tarrytown, New York facilities (the Facility) for a purchase price of $720.0 million. We occupy a significant portion of the Facility, with the remaining rentable area under leases to third-party tenants. In accordance with the terms of the Purchase Agreement, we paid $57.0 million toward the purchase price to BMR in December 2016.

On March 3, 2017, we entered into a Participation Agreement with Banc of America Leasing & Capital LLC (BAL), as lessor, and a syndicate of lenders (collectively, the Participants). The Participation Agreement provided for lease financing in connection with the acquisition by BAL of the Facility and our lease of the Facility from BAL. On March 3, 2017, we assigned our right to take title to the Facility under the Purchase Agreement to BAL, and the Participants advanced $720.0 million, which was used by BAL to finance the purchase price for the Facility and to reimburse us for the $57.0 million payment we made to BMR in December 2016.

On March 3, 2017, we entered into a lease agreement (the Lease) with BAL, pursuant to which we have leased the Facility from BAL for a five-year term. As a result of entering into the lease agreement, certain parts of the Facility became subleased from us by existing third-party tenants. The Lease requires us to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Lease in an amount equal to a variable rate per annum based on the one-month London Interbank Offered Rate (LIBOR), plus an applicable margin that varies with our debt rating and total leverage ratio.

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

The Participation Agreement and the Lease contain financial and operating covenants, which are substantially similar to the covenants set forth in our Credit Facility. We were in compliance with all covenants of the Participation Agreement and the Lease as of September 30, 2017.

Funding Requirements

The amount we need to fund operations will depend on various factors, including revenues from net product sales, the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations (in particular those with Sanofi and Bayer). We believe that our existing capital resources, borrowing availability under our revolving credit facility, funds generated by anticipated EYLEA net product sales, and, as described above under "Collaboration Agreements," funding for reimbursement of research and development costs that we are entitled to receive under our collaboration agreements, will enable us to meet our projected operating needs for the foreseeable future.

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. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi is responsible for funding up to $130.0 million of our antibody discovery activities in 2017. Our Antibody Discovery Agreement with Sanofi will end on December 31, 2017 and, therefore, funding from Sanofi under the Antibody Discovery Agreement will cease after 2017. See "Collaboration Agreements - Collaborations with Sanofi - *Antibodies*" above for further information.

We anticipate continuing to incur substantial commercialization costs for EYLEA, Dupixent, Praluent, and Kevzara. 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, regulatory approval of additional product candidates, and whether we may be required to pay additional royalties or share the profits from sales of products pursuant to our license or collaboration agreements or otherwise.

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.

Future Impact of Recently Issued Accounting Standards

See Note 15 to our Condensed Consolidated Financial Statements for a summary of recently issued accounting standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 (filed February 9, 2017).

We have exposure to market risk for changes in interest rates, including the interest rate risk relating to our March 2017 variable rate Tarrytown, New York lease (as described in Item 2. "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 partially offset by our investments in marketable securities. In addition, beginning in the second quarter of 2017, we began to further manage our interest rate exposure through the use of derivative instruments. All of our derivative instruments are utilized for risk management purposes, and are not used for trading or speculative purposes. We continue to monitor our interest rate risk and may utilize additional derivative instruments and/or other strategies in the future to further mitigate our interest rate exposure.

We have hedged a portion of our floating interest rate exposure using interest rate swap and interest rate cap contracts (see Note 11 to our Condensed Consolidated Financial Statements). The following table summarizes the notional amounts of our outstanding interest rate swap and cap contracts as of September 30, 2017:

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

ITEM 4. 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 report. 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.

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 September 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business, including those described in our Annual Report on Form 10-K for the year ended December 31, 2016 (filed February 9, 2017), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017 (filed May 4, 2017), our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017 (filed August 3, 2017), and those described below. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see Part II, Item 1A. "Risk Factors," including the discussion under the headings entitled "Risks Related to Intellectual Property and Market Exclusivity," "Regulatory and Litigation Risks," and "Risks Related to Our Common Stock."

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

As previously reported, on September 25, 2013, we commenced patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting our European Patent No. 1,360,287 (the '287 Patent) and our European Patent No. 2,264,163 (the '163 Patent), each of which concerns genetically engineered mice capable of producing chimeric antibodies that are part human and part mouse. On February 1, 2016, the court issued a final judgment, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However,

the court invalidated the '287 and '163 Patents on the ground of insufficiency. The hearing for our appeal and Kymab's cross-appeal was held on October 17 - 20, 2017.

As previously reported, on March 11, 2014, we commenced patent infringement litigation against Merus B.V. in the United States District Court for the Southern District of New York, asserting our U.S. Patent No. 8,502,018 (the '018 Patent), which concerns genetically engineered mice capable of producing chimeric antibodies that are part human and part mouse. On November 21, 2014, the United States District Court for the Southern District of New York issued its Opinion and Order on Claim Construction in the '018 Patent infringement litigation, in which it held the '018 Patent invalid and not infringed. On November 2, 2015, the United States District Court for the Southern District of New York issued an opinion and order finding that the '018 Patent was procured by inequitable conduct, thus rendering it unenforceable. On July 27, 2017, the United States Court of Appeals for the Federal Circuit (the Federal Circuit) affirmed the District Court's decision regarding inequitable conduct without deciding the issues of validity and infringement. On September 12, 2017, we submitted a petition for panel rehearing and/or rehearing *en banc* in the Federal Circuit. On November 2, 2017, Merus filed its response to our petition.

Proceedings Relating to Praluent (alirocumab) Injection

As previously reported, in the United States, Amgen Inc. has asserted a number of U.S. patents, which were subsequently narrowed to U.S. Patent Nos. 8,829,165 (the '165 Patent) and 8,859,741 (the '741 Patent), and seeks a permanent injunction to prevent us and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, Commercializing) Praluent. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. A jury trial in this litigation was held in the United States District Court for the District of Delaware (the District Court) from March 8 to March 16, 2016. During the course of the trial, the District Court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of Regeneron and the Sanofi defendants that there was no willful infringement of the asserted patent claims by Regeneron or the Sanofi defendants. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On January 3, 2017, the District Court issued a final opinion and judgment, denying our and the Sanofi defendants' motions for new trial and judgment as a matter of law. On October 5, 2017, the Federal Circuit reversed in part the District Court's decision, remanded for a new trial on the issues of written description and enablement, and vacated the District Court's permanent injunction. In addition, it affirmed the District Court's ruling that Amgen's patents were not obvious. The Federal Circuit further concluded that we and the Sanofi defendants were not entitled to judgment as a matter of law on the issues of written description and enablement on this record.

As previously reported, on July 25, 2016, Amgen filed a lawsuit for infringement of its European Patent No. 2,215,124 (the '124 Patent) against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf, Germany, seeking a permanent injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages. Oral hearing on this infringement lawsuit was held on October 19, 2017.

Proceedings Relating to Dupixent (dupilumab) Injection

As previously reported, on March 23, 2017, we, 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 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 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 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. The Additional IPR Petitions are still pending.

As previously reported, on April 5, 2017, Immunex Corporation filed a complaint against us, 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 our 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 us and the Sanofi parties. On June 28, 2017, we 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 jury trial has been scheduled to start on March 19, 2019.

Proceedings Relating to Shareholder Derivative Claims

As previously reported, on or about December 15, 2015, we received a shareholder litigation demand upon our board of directors made by a purported Regeneron shareholder. On or about November 3, 2017, we received a second shareholder litigation demand upon our board of directors made by another purported Regeneron shareholder, which is substantially similar to the December 15, 2015 shareholder litigation demand. The demands assert that the then current and certain former non-employee members of the board of directors and the Chairman of the board of directors excessively compensated themselves in 2013 and 2014. The demands request that our board of directors investigate and bring legal action against these directors for breach of fiduciary duty, unjust enrichment, and corporate waste, and implement internal controls and systems designed to prohibit and prevent similar actions in the future. Our board of directors is evaluating the impact of the New York Supreme Court's decision pertaining to the motion to dismiss filed by the defendants in the shareholder derivative litigation (discussed in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017 (filed August 3, 2017)) on the board's response to these demands.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Commercialization of EYLEA

We are substantially dependent on the success of EYLEA. If we or Bayer are unable to continue to successfully commercialize EYLEA, our business, prospects, operating results, and financial condition will be materially harmed.

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the nine months ended September 30, 2017 and 2016, EYLEA net sales in the United States represented 64% and 68% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

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

- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to differentiate EYLEA from Lucentis® (ranibizumab) and other competitive products, and the willingness of retinal specialists and patients to switch from Lucentis or off-label use of repackaged Avastin® (bevacizumab) to EYLEA or to start treatment with EYLEA;
- sufficient coverage of, and reimbursement for, EYLEA by third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development;
- the results of post-approval studies of EYLEA (whether conducted by us or by others and whether mandated by regulatory agencies or voluntary), and studies of other products that could implicate VEGF inhibitors as a class or are perceived to do so, as well as the results of the studies investigating nesvacumab (an antibody to angiopoietin-2) co-formulated with aflibercept conducted by us and Bayer;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices; and
- risks associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below.

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

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

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

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

Serious complications or serious, unexpected side effects in connection with the use of EYLEA could materially harm our business, prospects, operating results, and financial condition. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below.

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

Our sales in the United States of EYLEA are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in large part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. For example, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-label, repackaged Avastin rather than Lucentis for the treatment of wet AMD. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of EYLEA. Economic pressure on state budgets may also have a similar impact. In addition, other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products - *The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

The commercial success of EYLEA is subject to strong competition.

The market for eye disease products is very competitive. For example, Novartis AG and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of various eye indications. Lucentis is approved in one or more jurisdictions for the treatment of wet AMD, macular edema following RVO (including CRVO and BRVO), DME, diabetic retinopathy, and mCNV. Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Pfenex Inc. is developing PF582 (a Phase 1b/2a trial in patients with wet AMD has been completed), Formycon AG (in collaboration with Bioeq GmbH) is developing FYB201 (currently in a Phase 3 trial in patients with wet AMD), and Samsung Bioepis is developing SB11 (currently in a Phase 3 trial in patients with wet AMD).

Other competitive or potentially competitive products include Allergan, Plc's Ozurdex® (dexamethasone) (approved by the FDA for the treatment of macular edema following RVO and for the treatment of DME) and Alimera Sciences, Inc's Iluvien® (fluocinolone ophthalmic implant) (approved by the FDA for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids. Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, and RVO, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, Genentech/Roche is developing a Lucentis port delivery system implant (currently in a Phase 2 study in patients with wet AMD). Novartis is developing RTH258 (ESBA1008), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and announced in June 2017 that two Phase 3 studies of RTH258 met their primary endpoint of non-inferiority to EYLEA. Allergan is developing abicipar pegol for wet AMD and related conditions (currently studied in Phase 3 trials against Lucentis as a comparator drug). Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, Ang2). Genentech/Roche is developing a bi-specific antibody (RG7716) targeting both VEGF and Ang2 for wet AMD and DME (currently in Phase 2 trials for both indications). Competitors are also developing eye-drop formulations, devices, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

In addition, ophthalmologists are using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, Avastin, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged Avastin presents a significant competitive challenge in these indications. Competitors (including Amgen) are also developing a biosimilar version of Avastin. Avastin is also being evaluated in eye diseases in clinical trials in certain countries. Furthermore, Lucentis and off-label use of repackaged Avastin present significant competitive challenges as doctors and patients have had significant experience using these medicines. The relatively low cost of repackaged Avastin in treating patients may exacerbate the competitive challenge which EYLEA faces in the eye indications for which it is approved.

Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, and there is a risk that third parties may attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications. We are aware of claims by third parties, including those based on published clinical data, that ZALTRAP (ziv-aflibercept) may be safely administered to the eye.

See also "Risks Related to Commercialization of Products - *We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects*" below.

We rely on our collaboration with Bayer for commercializing EYLEA.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA outside the United States.

Under the terms of our license and collaboration agreement with Bayer (which is terminable by Bayer at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination), we rely on Bayer for sales, marketing, and distribution of EYLEA in countries outside the United States. If we and Bayer are unsuccessful in continuing to commercialize EYLEA, our ability to sustain profitability would be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA, particularly outside the United States. For additional information regarding our collaboration with Bayer, see "Risks Related to Our Reliance on Third Parties - *If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed*" below.

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

Our sales of EYLEA in the United States and Bayer's sales of EYLEA in other countries may be reduced if EYLEA is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or 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. Prices for EYLEA 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 our sales of EYLEA in the United States may be reduced if EYLEA marketed in those nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of EYLEA in a particular market or reduce our or Bayer's sales, thereby adversely affecting our results of operations. In addition, there 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 EYLEA sales could be reduced.

Risks Related to Commercialization of Our Antibody-based Products (Dupixent, Praluent, and Kevzara)

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

We expect that the commercial success of Dupixent, Praluent, and Kevzara will depend on many factors, including the following (as applicable):

- effectiveness of the commercial strategy in and outside the United States for the marketing of these products, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- our and Sanofi's ability to differentiate these products from competitive products (including, in the case of Dupixent, Pfizer Inc.'s Xeljanz® (tofacitinib) and Eli Lilly and Company's Olumiant® (baricitinib); in the case of Praluent, Amgen's Repatha® (evolocumab); and, in the case of Kevzara, Genentech/Roche's Actemra® (tocilizumab)), as well as product candidates currently in clinical development (such as, in the case of Dupixent, the antibody product candidates being developed by Roche, LEO Pharma Inc., AstraZeneca PLC, Galderma S.A., AnaptysBio, Inc., and Amgen);
- the outcome of the pending patent infringement proceedings relating to Dupixent (described further in Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, and this report), and other risks relating to Dupixent 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 patent infringement proceedings relating to Praluent initiated by Amgen against us and Sanofi (described further in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2016 and Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, and this report), and other risks relating to Praluent 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;
- sufficient coverage of, and reimbursement for, these products by third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- payer restrictions on eligible patient populations and the reimbursement process, both in the United States and abroad;
- the results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary (including, in the case of Praluent, the ongoing ODYSSEY OUTCOMES trial prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit), and studies of other products that could implicate an entire class of products or are perceived to do so;
- our ability to meet the demand for commercial supplies of these products;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices; and

- maintaining and successfully monitoring commercial manufacturing arrangements for these products with parties who perform fill/finish or other steps in the manufacture of these products to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities.

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

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

We and Sanofi are subject to significant ongoing regulatory obligations and oversight with respect to Dupixent, Praluent, and Kevzara for their currently approved indications in the United States, EU, and other countries. If we or Sanofi fail to maintain regulatory compliance for Dupixent, Praluent, or Kevzara for the currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies, such as, in the case of Praluent, the ongoing ODYSSEY OUTCOMES trial, or for any of the other reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain*"), 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 - *If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales*" below.

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

Serious complications or serious, unexpected side effects in connection with the use of Dupixent, Praluent, or Kevzara could materially harm our business, prospects, operating results, and financial condition. For additional information about some of these risks, see "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below.

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

Sales in the United States of Dupixent, Praluent, and Kevzara are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of Dupixent, Praluent, and Kevzara in other countries are dependent, in large part, on similar reimbursement mechanisms and programs in those countries.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process, including by means of required prior authorizations and utilization management criteria. For example, pharmacy benefit management companies often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one pharmacy benefit management company to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of Dupixent, Praluent, and Kevzara. If Dupixent, Praluent, or Kevzara is not included within an adequate number of formularies, adequate reimbursement levels are not provided, the eligible insured patient population for Dupixent, Praluent, or Kevzara is limited, or a key payer refuses to provide reimbursement for Dupixent, Praluent, or Kevzara in a particular jurisdiction altogether, this could have a material adverse effect on our and Sanofi's ability to commercialize the applicable product.

In the United States, there also is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of Dupixent, Praluent, and Kevzara. Since Dupixent, Praluent, and Kevzara are too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers in the United States and other countries, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize the applicable product will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products - *The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

The commercial success of Dupixent, Praluent, and Kevzara is subject to strong competition.

There is significant actual and potential future competition for Dupixent. A number of companies are developing antibodies that, if approved, may compete with Dupixent in its current or potential future indications, including Roche (in collaboration with Dermira, Inc.) (an antibody against IL-13); LEO Pharma (in collaboration with AstraZeneca) (IL-13 antibody tralokinumab being developed in the atopic dermatitis indication); AstraZeneca (antibodies against IL-4R and IL-5R, as well as IL-13 antibody tralokinumab being developed in the asthma indication); Galderma (an antibody against IL-31R); AnaptysBio (an antibody against IL-33); and Amgen (in collaboration with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). GSK's Nucala® (mepolizumab) and Teva's Cinqair® (reslizumab), both of which are antibodies against IL-5, may also compete with Dupixent in its current or potential future indications. We are also aware of companies developing or marketing small molecules that may compete with Dupixent in its current or potential future indications. These include Pfizer's Eucrisa™ (crisaborole), a topical ointment that competes with Dupixent in the atopic dermatitis indication; and JAK inhibitors, such as AbbVie Inc.'s upadacitinib, Pfizer's Xeljanz, and Eli Lilly's Olumiant.

There also is significant actual and potential future competition for Praluent. Amgen's PCSK9 program is currently the most advanced of the competitors, having already received regulatory approvals in jurisdictions including the U.S., the EU, and Japan for its PCSK9 inhibitor Repatha. Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Other companies with development programs for injectables against PCSK9 include Alnylam Pharmaceuticals, Inc. (in collaboration with The Medicines Company), which has a clinical program underway with inclisiran, an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including oral products and vaccines. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including Praluent. These include bempedoic acid, which is being developed by Esperion Therapeutics, Inc.; gemcabene, which is being developed by Gemphire Therapeutics, Inc.; and an inhibitor of cholesterylester transfer protein (CETP), which is being developed by DalCor Pharmaceuticals.

Kevzara also faces competition from actual and potential future products. Genentech/Roche is marketing an antibody against IL-6R (Actemra) for the treatment of rheumatoid arthritis that competes with Kevzara. In addition, several other companies, including Alder Biopharmaceuticals, Inc. (in collaboration with Vitaeris Inc.), Ablynx, R-Pharm, and Bird Rock Bio, Inc. have antibodies against IL-6 or IL-6R in clinical development. Further, oral, small-molecule JAK inhibitors such as Pfizer's Xeljanz, Eli Lilly's Olumiant, and AbbVie's upadacitinib may pose a competitive threat for Kevzara.

We rely on our Antibody Collaboration with Sanofi for commercializing Dupixent, Praluent, and Kevzara.

In accordance with the terms of our Antibody Collaboration with Sanofi, we have elected to co-promote Dupixent, Kevzara, and Praluent with Sanofi in the United States. As such, we continue to rely in part on Sanofi's sales and marketing organization in the United States. If we and Sanofi fail to coordinate our United States sales and marketing efforts effectively, sales of Dupixent, Praluent, or Kevzara (as applicable) may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent, Praluent, and Kevzara in the United States. For example, Sanofi records product sales for Dupixent, Praluent, and Kevzara in the United States, serves as the lead regulatory party for certain products and product candidates included in the Antibody Collaboration (*e.g.*, is responsible for regulatory filings and negotiations relating to such products and product candidates) in the United States, and may lead negotiations with payors relating to such products and product candidates. We also rely on Sanofi for sales, marketing, and distribution of Dupixent, Praluent, and Kevzara in countries outside the United States. If we or Sanofi are unsuccessful in commercializing Dupixent, Praluent, or Kevzara, or if Sanofi terminates the Antibody Collaboration with us, our business, prospects, operating results, and financial condition may be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for Dupixent, Praluent, and Kevzara. Therefore, termination of our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of Dupixent, Praluent, and Kevzara, particularly outside the United States. For additional information regarding our Antibody Collaboration with Sanofi, see "Risks Related to Our Reliance on Third Parties - *If any of our collaborations with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed*" below.

Sales of Dupixent, Praluent, and Kevzara recorded by Sanofi could be reduced by imports from countries where these products may be available at lower prices.

Sales of Dupixent, Praluent, and Kevzara recorded by Sanofi in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under our Antibody Collaboration with Sanofi 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 Antibody Collaboration with Sanofi, pricing and reimbursement for Dupixent, Praluent, and Kevzara outside the United States is the responsibility of Sanofi. Prices for Dupixent, Praluent, and Kevzara 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 Dupixent, Praluent, and Kevzara in the United States that are recorded by Sanofi may be reduced if the applicable product marketed in those bordering nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of Dupixent, Praluent, and Kevzara in a particular market or the sales recorded by Sanofi, thereby adversely affecting our results of operations. 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 Dupixent, Praluent, or Kevzara sales could be reduced.

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

If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.

We cannot sell or market products without regulatory approval. If we do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products, the value of our company and our business, prospects, operating results, and financial condition will be materially harmed. If we are unable to obtain regulatory approval for our product candidates, or if we are materially delayed in doing so, our business, prospects, operating results, and financial condition may be materially harmed.

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

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain

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

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

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional inspections or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators, or third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for Kevzara, which referred to certain

deficiencies identified during a routine cGMP inspection of the Sanofi facility in Le Trait, France where Kevzara is filled and finished; while the BLA for Kevzara has since been approved by the FDA, this delayed the FDA approval of Kevzara. For additional information, see "Risks Related to Manufacturing and Supply - *If we fail to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates, we could incur substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.*" Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

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

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (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 Good Laboratory Practices (GLPs) or GCPs. A clinical trial may fail because it did not include and retain a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

Furthermore, some of our product candidates (such as cemiplimab) 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 (REGN2222), an antibody to respiratory syncytial virus (RSV), did not meet its primary endpoint of preventing medically-attended RSV infections in infants and that we planned to discontinue 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. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response Letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP as a first-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our antibody-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.

EYLEA is being studied in additional indications, and aflibercept is being studied as a combination product. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully develop and/or commercialize aflibercept. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like aflibercept (such as intraocular inflammation, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), which can cause injury to the eye and other complications. For example, in our Phase 3 trials of EYLEA in wet AMD, the most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. These and other complications or side effects could harm further development and/or commercialization of aflibercept.

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

The potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing ODYSSEY OUTCOMES trial. There is no guarantee that Praluent will meet the relevant endpoints of this trial. In addition, there are potential safety concerns associated with PCSK9 inhibitor antibodies such as Praluent that may limit our ability to further successfully develop and/or commercialize Praluent, including new-onset diabetes mellitus, injection-site reactions, hypersensitivity reactions, immunogenicity, demyelination, and changes in neurocognitive function.

There also are risks inherent in subcutaneous injections (which are used for administering our antibody-based products and product candidates, including Dupixent, Praluent, and Kevzara), such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. These and other complications or side effects could harm further development and/or commercialization of our antibody-based products and product candidates, including Dupixent, Praluent, or Kevzara.

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

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

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

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody-based product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

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

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

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

Risks Related to Intellectual Property and Market Exclusivity

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 1,360,287 was, and our European Patent No. 2,264,163 is, the subject of opposition proceedings in the EPO, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2016 and Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017. We have pending patent applications in 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* reexamination under the America Invents Act of 2011 or *ex parte* reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to damage awards if we are found to have infringed such patents or rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody-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 are currently party to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2016 and Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, and this report; and patent infringement proceedings relating to Dupixent, as described in Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, and this report. In addition, we are currently party to patent infringement proceedings initiated by us relating to our European Patent No. 1,360,287, our European Patent No. 2,264,163, and our U.S. Patent No. 8,502,018, all of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2016 and Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, and this report (as applicable).

We are aware of patents and pending patent applications owned by others that respectively claim antibodies to IL-4R and methods of treating conditions including atopic dermatitis and asthma with such antibodies; antibodies to IL-6R and methods of treating conditions including rheumatoid arthritis with such antibodies; antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies; and antibodies to PD-1 and methods of treating cancer with such antibodies. In addition to Dupixent (dupilumab), Praluent (alirocumab), and Kevzara (sarilumab), our late-stage antibody-based pipeline includes fasinumab, an antibody to NGF; and cemiplimab, an antibody to PD-1, intended for the treatment of certain cancer indications including advanced cutaneous squamous cell carcinoma. With respect to Dupixent, we are aware of certain patents owned by Immunex Corporation, a wholly owned subsidiary of Amgen. These patents include U.S. Patent No. 8,679,487 (currently subject to the patent infringement proceedings described in Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, and this report) and European Patent No. 2,292,665 (the '665 Patent) and are generally directed to antibodies that bind to IL-4R.

On September 30, 2016, Sanofi initiated a revocation proceeding to invalidate the U.K. counterpart of the '665 Patent in the United Kingdom. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the currently pending EPO opposition proceedings initiated by us and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions is currently scheduled for November 20, 2017. The original patent term of the Immunex patents is set to expire in 2021.

Although we do not believe that any of our late-stage antibody-based product candidates infringes any valid claim in these patents or patent applications, these other parties could initiate lawsuits for patent infringement and assert that their patents are valid and cover our 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 product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our products or product candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our products or product candidates infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business.

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

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

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

Under the federal PPACA, enacted in 2010, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened.

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

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes

in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

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

Our manufacturing facilities would be inadequate to produce the active pharmaceutical ingredients of (a) our current marketed products, including EYLEA, Dupixent, Praluent, and Kevzara, and (b) our antibody-based product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to rely on our collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. As we increase our production in anticipation of potential regulatory approval for our late-stage antibody-based product candidates, our current manufacturing capacity will likely not be sufficient, and we may depend on our collaborators or contract manufacturers, to produce adequate quantities of drug material for both commercial and clinical purposes. We rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our collaborators, contract manufacturers, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and late-stage product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

We have acquired and are renovating a 400,000 square foot facility in Limerick, Ireland to expand our manufacturing capacity to support our global supply chain. In the future, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing activities. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our late-stage product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures and various regulatory approvals and permits. In addition, the Limerick, Ireland facility remains subject to securing certain governmental permits, and there is no guarantee that we will be able to obtain the remaining required permits in the contemplated timeframe, or at all. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, including EYLEA, Dupixent, Praluent, and Kevzara, and could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products in our Rensselaer, New York facilities and at additional facilities (such as the Limerick, Ireland facility) in the future, or to utilize third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of EYLEA, Dupixent, Praluent, or Kevzara do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties.

We have large-scale manufacturing operations in Rensselaer, New York and are in the process of building a large-scale manufacturing facility in Limerick, Ireland. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

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

We currently manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, acts of war or terrorism, or other problems.

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

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, 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 ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

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

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

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facility in Rensselaer, New York, including EYLEA, Dupixent, Praluent, Kevzara, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. For example, on October 28, 2016, the FDA issued a Complete Response Letter relating to the BLA for Kevzara, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi fill-and-finish facility in Le Trait, France. While the BLA for Kevzara has since been approved by the FDA, this delayed the FDA approval of Kevzara. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Risks Related to Commercialization of Products

We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payers and on our and our collaborators' ability to successfully manufacture, market and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

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

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

For a description of additional risks relating specifically to the commercialization of EYLEA, Dupixent, Praluent, and Kevzara, see above under "Risks Related to Commercialization of EYLEA" and "Risks Related to Commercialization of Our Antibody-based Products (Dupixent, Praluent, and Kevzara)" (as applicable).

Our marketed products are subject to significant competition, and our product candidates or new indications for our marketed products, if any are approved for marketing, may face significant competition.

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve commercialization of our product candidates, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

The market for eye disease products is very competitive, as described in greater detail above under "Risks Related to Commercialization of EYLEA - *The commercial success of EYLEA is subject to strong competition*."

There is also significant actual and potential future competition for Dupixent, Praluent, and Kevzara, as described in greater detail above under "Risks Related to Commercialization of Our Antibody-based Products (Dupixent, Praluent, and Kevzara) - *The commercial success of Dupixent, Praluent, and Kevzara is subject to strong competition*."

Our earlier-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune* technology. Our antibody generation technologies and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody-based products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody-based product candidate against NGF. For cemiplimab, there are several competitors that are marketing or developing antibodies against PD-1 and/or PDL-1, including Bristol-Myers Squibb Company (Opdivo® (nivolumab)), Merck & Co., Inc.'s (Keytruda® (pembrolizumab)), Roche (Tecentriq® (atezolizumab)), AstraZeneca (Imfinzi® (durvalumab)), Pfizer (Bavencio® (avelumab)), Novartis (PDR001), and TESARO, Inc. (TSR-042). We are also aware of several companies developing or marketing small molecules that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our products candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition.

Our future revenues and profitability will be adversely affected in a material manner if United States and foreign governmental payers, private third-party insurers and payers (such as health maintenance organizations and pharmacy benefit management companies), and other third-party payers, including Medicare and Medicaid, do not adequately defray or reimburse the cost of our products to the patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payers more expensive for patients. Third-party payers may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply and regulatory review of such products. Given cost sensitivities in many health care systems, our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our products, we must, among other things, maintain our FDA registration and our National Drug Code,

maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and CMS. There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage) of our current and future products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process (including by means of required prior authorizations and utilization management criteria). In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost-containment and other measures that are likely to adversely affect the amount of reimbursement for our current and future products. The full effects of this legislation depend on a number of factors, many of which are beyond our control, including new regulations and guidance issued by CMS and other federal and state agencies. Some states are also considering legislation that would control the prices 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 products.

There is a risk that third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse our current and future products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

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

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the three months ended September 30, 2017, product sales to three customers accounted on a combined basis for 99% of our total gross product revenue. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

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

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

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

For additional risks relating to commercialization of EYLEA, Dupixent, Praluent, and Kevzara outside the United States, see also "Risks Related to Commercialization of EYLEA - *We rely on our collaboration with Bayer for commercializing EYLEA*" and "Risks Related to Commercialization of Our Antibody-based Products (Dupixent, Praluent, and Kevzara) - *We rely on our Antibody Collaboration with Sanofi for commercializing Dupixent, Praluent, and Kevzara*" (as applicable).

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.

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

As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any "transfers of value" made to U.S. prescribers and certain other healthcare providers and teaching hospitals. Information provided by companies is aggregated and posted annually on an "Open Payments" website, which is managed by CMS, the agency responsible for implementing these disclosure requirements. We will need to continue to dedicate significant resources to comply with these requirements and to be prepared to comply with additional reporting obligations outside of the United States that may apply in the future. The PPACA also includes various provisions designed to strengthen fraud-and-abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, several states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside of the United States are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

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

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

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

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

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

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

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

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

Risks associated with our operations outside of the United States could adversely affect our business.

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "*Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*");
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- our ability to deploy overseas funds in an efficient manner;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

For example, on June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, the British government has begun negotiating the terms of the United

Kingdom's future relationship with the EU. We do not know to what extent Brexit will impact the business and regulatory environment in the United Kingdom, the rest of the EU, or other countries. Changes impacting our ability to conduct business in the United Kingdom or other EU countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities that involve significant management judgment for uncertain tax positions. The Internal Revenue Service or other domestic or foreign taxing authorities may disagree with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns. Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country and changes in tax laws and regulations. Changes in tax laws of various jurisdictions in which we do business could also result from the base erosion and profits shifting, or BEPS, recommendations by the Organization for Economic Co-operation and Development. If these recommendations (or other changes in law) were adopted by the countries in which we do business, it could adversely affect our provision for income tax and our current rate.

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

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with research institutions, including the Geisinger Health System, which are subject to such regulations. Regeneron is not currently classified as a covered entity or business associate under HIPAA and thus is not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs and research collaborations outside the U.S. (such as RGC's collaboration with U.K. Biobank and GSK) may implicate international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it. Our activities outside the U.S. impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

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

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Risks Related to Our Reliance on Third Parties

If any of our collaborations with Sanofi is terminated, our business, prospects, operating results, and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from Sanofi to support certain research and development programs, including our immuno-oncology research and development programs. Sanofi has committed to reimburse us for up to $825.0 million of the costs of our efforts to identify and validate potential immuno-oncology targets and develop fully-human therapeutic antibodies against such targets under the IO Discovery and Development Agreement over the term of the IO Discovery and Development Agreement. Sanofi also initially funds almost all of the development expenses incurred in connection with the clinical development of product candidates for which Sanofi is the principal controlling party under our IO Collaboration. In addition, Sanofi initially funds half of the development expenses incurred in connection with the clinical development of product candidates for which we are the principal controlling party under our IO Collaboration. We rely on Sanofi to fund these activities. In addition, with respect to those antibodies that Sanofi elects to co-develop with us under our Antibody Collaboration (such as Dupixent, Praluent, Kevzara, and REGN3500) or for which Sanofi is the principal controlling party under our IO Collaboration, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we also rely on Sanofi to lead (i) the commercialization efforts to support all of the antibody-based products that are co-developed by Sanofi and us under our Antibody Collaboration and (ii) the commercialization efforts outside the Unites States to support all products that are co-developed by Sanofi and us under our IO Collaboration (as well as the commercialization efforts in the United States to support all products for which Sanofi is the principal controlling party under our IO Collaboration).

If Sanofi does not elect to co-develop the product candidates discovered under our Antibody Collaboration or our IO Collaboration or opts out of their development, unless we enter into a collaboration agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody-based products. For example, under our Antibody Collaboration, Sanofi has elected not to continue co-development of fasinumab and trevogrumab, and decided not to opt in to the evinacumab and other programs. In addition, as previously reported, after 2017 we will be required to fund our antibody discovery activities and the research and preclinical development activities of our drug candidates, as Sanofi’s funding obligations under the Antibody Discovery Agreement will cease.

If Sanofi terminates the License and Collaboration Agreement or the IO Collaboration or fails to comply with its payment obligations under any of our collaborations, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. If Sanofi does not perform its obligations with respect to the product candidates that it elects to co-develop, our ability to develop, manufacture, and commercialize these product candidates will be significantly adversely affected. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for products commercialized under our Antibody Collaboration, such as Dupixent, Praluent, and Kevzara (see also "Risks Related to Commercialization of Products - *If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the License and Collaboration Agreement would create substantial new and additional risks to the successful development and commercialization of Dupixent, Praluent, and Kevzara, particularly outside the United States.

If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to develop EYLEA and commercialize EYLEA outside the United States in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer to assist with the development, and particularly the commercialization outside the United States, of EYLEA. Under our agreement with them, Bayer is required to fund approximately half of the development expenses incurred by both companies in connection with the global EYLEA development program. As the EYLEA program continues, we will continue to rely on Bayer to assist with funding the EYLEA development program, continue to lead the development of EYLEA outside the United States, obtain and maintain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen Pharmaceuticals Co. Ltd. pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate. We cannot assure you that regulatory approvals will be received for EYLEA in additional indications outside the United States or that EYLEA will be successfully commercialized outside the United States. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our collaborator, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of EYLEA outside the United States and result in substantial additional costs to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also "Risks Related to Commercialization of Products - *If we need to establish commercial capabilities outside the United States and are unable to do so, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful development and commercialization of EYLEA, particularly outside the United States.

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

We depend upon third-party collaborators, including Sanofi, Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers, fill/finish, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these third parties in connection with the commercialization of our marketed products and our late-stage product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators' arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer; and Neil Stahl, Ph.D., our Executive Vice President, Research and Development. As we continue to commercialize EYLEA, Dupixent, Praluent, and Kevzara and, assuming the receipt of required regulatory approvals, other products, we are also highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses, which may 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.

Beginning in 2012, we reported profitability; prior to that, we generally incurred net losses. If we cannot sustain profitability, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products on an ongoing basis, including our sales of EYLEA, and our share of the profits from Bayer's sales of EYLEA outside the United States, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

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

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the commercialization of 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 $720.0 million lease financing for our existing corporate headquarters and other rentable area consisting of approximately 170 acres of predominately office buildings and laboratory space located in the towns of Mount Pleasant and Greenburgh, NY, which will become due and payable in full on the five-year anniversary of the closing date unless extended with the consent of all the participants and subject to certain other conditions. Our ability to refinance or to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such

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

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

Our revenue from outside of the United States will increase as our products, whether marketed by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our company.

Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.

As of September 30, 2017, we had $792.1 million in cash and cash equivalents and $1,914.2 million in marketable securities (including $88.0 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- net product sales of our marketed products, in particular EYLEA and Dupixent, 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 and Dupixent;
- whether our net products sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the 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;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been maintaining its percentage ownership of our Common Stock but has previously publicly disclosed that it may opportunistically increase its percentage ownership of our Common Stock. As a result, the public float of our Common Stock (*i.e.*, the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In 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 September 30, 2017, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 48.2% 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 September 30, 2017. As of September 30, 2017, Sanofi beneficially owned 23,880,537 shares of our Common Stock, representing approximately 22.6% 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. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase (subject to market conditions, including the price and availability of shares of our Common Stock, and legal and regulatory requirements) additional shares of our Common Stock to maintain and opportunistically increase its beneficial ownership on a percentage basis up to the maximum allowed under the "standstill" provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2017, holders of Class A Stock held 15.3% 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 September 30, 2017:

- our current executive officers and directors beneficially owned 10.3% 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 September 30, 2017, and 21.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2017; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 48.2% 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 September 30, 2017. In addition, these five shareholders plus our Chief Executive Officer held approximately 53.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2017.

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 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). 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.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual shareholder meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;

- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder," a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management.*"

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our License and Collaboration Agreement with Sanofi relating to our Antibody Collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our company.

Similarly, under our 2016 ANG2 license and collaboration agreement with Bayer, Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of our company or acquiring more than 20% of our outstanding Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our company; (iii) the acquisition by a third party or a group of third parties (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer; or (v) other specified events, such as a liquidation or dissolution of our company.

Further, pursuant to the 2016 collaboration agreement between us and Teva, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of our company or acquiring more than 5% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving us; (iv) the acquisition by a third party or a group of third parties of more than 30% of the voting power of our outstanding Class A Stock and Common Stock (taken together); (v) the date of any issuance of shares of capital stock by us that would result in another party having more than 10% of the voting power of our outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Teva; or (vi) other specified events, such as a liquidation or dissolution of our company.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our company. Also, stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan, 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 6. EXHIBITS

(a) Exhibits

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101	Interactive Data File
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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SIGNATURE

Pursuant to the requirements 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: November 8, 2017

By: /s/ Robert E. Landry

Robert E. Landry
Senior Vice President, Finance and
Chief Financial Officer
(Duly Authorized Officer)

Exhibit 31.1

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 quarterly report on Form 10-Q 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: November 8, 2017

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

Exhibit 31.2

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 quarterly report on Form 10-Q 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: November 8, 2017

/s/ Robert E. Landry

Robert E. Landry

Senior Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32

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 Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2017 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)

November 8, 2017

/s/ Robert E. Landry

Robert E. Landry

Senior Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

November 8, 2017