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, 2016**

OR

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

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	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	_____

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, 2016:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,911,456
Common Stock, $.001 par value	103,558,843

REGENERON PHARMACEUTICALS, INC.
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, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 920,359	$ 809,102
Marketable securities	488,032	236,121
Accounts receivable - trade, net	1,332,071	1,152,489
Accounts receivable from Sanofi	124,107	153,152
Accounts receivable from Bayer	187,694	162,152
Inventories	345,620	238,578
Prepaid expenses and other current assets	103,806	163,501
Total current assets	3,501,689	2,915,095
Marketable securities	777,906	632,162
Property, plant, and equipment, net	1,872,167	1,594,120
Deferred tax assets	655,552	461,945
Other assets	20,705	5,810
Total assets	$ 6,828,019	$ 5,609,132
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 714,916	$ 644,112
Deferred revenue from Sanofi, current portion	105,041	101,573
Deferred revenue - other, current portion	137,642	51,914
Other current liabilities	3,586	13,563
Total current liabilities	961,185	811,162
Deferred revenue from Sanofi	529,791	582,664
Deferred revenue - other	327,868	82,015
Facility lease obligations	382,228	362,919
Other long-term liabilities	135,700	115,535
Total liabilities	2,336,772	1,954,295
Stockholders' equity:		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,911,456 in 2016 and 1,913,776 in 2015	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 107,311,675 in 2016 and 106,378,001 in 2015	107	106
Additional paid-in capital	3,314,982	3,099,526
Retained earnings	1,495,107	852,700
Accumulated other comprehensive (loss) income	(2,899)	8,572
Treasury stock, at cost; 3,761,628 shares in 2016 and 3,642,820 in 2015	(316,052)	(306,069)
Total stockholders' equity	4,491,247	3,654,837
Total liabilities and stockholders' equity	$ 6,828,019	$ 5,609,132

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,	
	2016	**2015**	**2016**	**2015**
Statements of Operations				
Revenues:				
Net product sales	$ 857,468	$ 737,562	$ 2,475,869	$ 1,939,954
Sanofi collaboration revenue	144,392	224,735	527,500	593,201
Bayer collaboration revenue	191,298	157,596	562,786	415,679
Other revenue	26,964	17,529	67,445	56,817
	1,220,122	1,137,422	3,633,600	3,005,651
Expenses:				
Research and development	543,047	425,924	1,573,089	1,159,367
Selling, general, and administrative	270,045	209,993	851,760	543,572
Cost of goods sold	29,901	67,199	150,090	170,624
Cost of collaboration and contract manufacturing	14,327	41,884	74,923	111,254
	857,320	745,000	2,649,862	1,984,817
Income from operations	362,802	392,422	983,738	1,020,834
Other income (expense):				
Investment income	3,301	2,140	8,351	3,973
Interest and other expense, net	(222)	(1,273)	(3,801)	(26,999)
	3,079	867	4,550	(23,026)
Income before income taxes	365,881	393,289	988,288	997,808
Income tax expense	(101,077)	(182,891)	(345,881)	(516,746)
Net income	$ 264,804	$ 210,398	$ 642,407	$ 481,062
Net income per share - basic	$ 2.53	$ 2.04	$ 6.14	$ 4.68
Net income per share - diluted	$ 2.27	$ 1.82	$ 5.51	$ 4.18
Weighted average shares outstanding - basic	104,833	103,348	104,586	102,825
Weighted average shares outstanding - diluted	116,466	115,944	116,567	115,144
Statements of Comprehensive Income				
Net income	$ 264,804	$ 210,398	$ 642,407	$ 481,062
Other comprehensive income (loss):				
Unrealized loss on marketable securities, net of tax	(8,103)	(11,432)	(11,471)	(44,530)
Comprehensive income	$ 256,701	$ 198,966	$ 630,936	$ 436,532

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,	
	2016	**2015**
Cash flows from operating activities:		
Net income	$ 642,407	$ 481,062
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	75,845	51,999
Non-cash compensation expense	405,320	300,657
Other non-cash charges and expenses, net	13,586	34,919
Deferred taxes	(190,327)	(65,975)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer, and trade accounts receivable	(176,079)	(462,943)
Increase in inventories	(99,706)	(66,254)
Decrease (increase) in prepaid expenses and other assets	34,857	(13,223)
Increase in deferred revenue	282,176	624,063
Increase in accounts payable, accrued expenses, and other liabilities	107,438	164,652
Total adjustments	453,110	567,895
Net cash provided by operating activities	1,095,517	1,048,957
Cash flows from investing activities:		
Purchases of marketable securities	(606,153)	(550,142)
Sales or maturities of marketable securities	192,091	265,995
Capital expenditures	(361,486)	(500,154)
Net cash used in investing activities	(775,548)	(784,301)
Cash flows from financing activities:		
Proceeds in connection with facility lease obligations	3,232	26,405
Repayments of convertible senior notes	(12,650)	(146,007)
Payments in connection with reduction of outstanding warrants	(242,117)	(523,487)
Proceeds from issuance of Common Stock	89,777	150,423
Payments in connection with Common Stock tendered for employee tax obligations	(46,954)	(71,673)
Excess tax benefit from stock-based compensation	—	305,551
Net cash used in financing activities	(208,712)	(258,788)
Net increase in cash and cash equivalents	111,257	5,868
Cash and cash equivalents at beginning of period	809,102	648,719
Cash and cash equivalents at end of period	$ 920,359	$ 654,587

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 periods are not necessarily indicative of the results for the full year. The December 31, 2015 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, 2015.

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

2. Product Sales

EYLEA® net product sales in the United States totaled $853.6 million and $734.4 million for the three months ended September 30, 2016 and 2015, respectively, and $2,465.4 million and $1,930.0 million for the nine months ended September 30, 2016 and 2015, respectively. In addition, ARCALYST® net product sales totaled $3.9 million and $3.2 million for the three months ended September 30, 2016 and 2015, respectively, and $10.5 million and $9.9 million for the nine months ended September 30, 2016 and 2015, respectively.

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, 2016 and 2015.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2015	$ 6,419	$ 48,313	$ 517	$ 55,249
Provision related to current period sales	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
Balance as of December 31, 2014	$ 3,083	$ 21,166	$ 532	$ 24,781
Provision related to current period sales	41,290	88,049	6,024	135,363
Credits/payments	(38,011)	(71,007)	(6,052)	(115,070)
Balance as of September 30, 2015	$ 6,362	$ 38,208	$ 504	$ 45,074

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

3. Collaboration Agreements

a. Sanofi

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

	Three Months Ended September 30,	
Sanofi Collaboration Revenue	**2016**	**2015**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 131,389	$ 205,114
Reimbursement of Regeneron commercialization-related expenses	65,703	53,341
Regeneron's share of losses in connection with commercialization of antibodies	(112,001)	(74,865)
Other	3,075	2,561
Total Antibody	88,166	186,151
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	36,226	18,584
Other	20,000	20,000
Total Immuno-oncology	56,226	38,584
	$ 144,392	$ 224,735

	Nine Months Ended September 30,	
Sanofi Collaboration Revenue	**2016**	**2015**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 469,223	$ 585,450
Reimbursement of Regeneron commercialization-related expenses	224,862	89,145
Regeneron's share of losses in connection with commercialization of antibodies	(333,530)	(143,583)
Other	9,094	7,683
Total Antibody	369,649	538,695
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	97,851	18,584
Other	60,000	20,000
Total Immuno-oncology	157,851	38,584
ZALTRAP®:		
Reimbursement of Regeneron research and development expenses	—	686
Other	—	15,236
Total ZALTRAP	—	15,922
	$ 527,500	$ 593,201

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 is obligated to fund up to $130.0 million of the Company's research activities in 2016. 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. During the three months ended September 30, 2016 and 2015, the Company recognized as additional research and development expense $27.9 million and $25.1 million, respectively, and during the nine months ended September 30, 2016 and 2015, the Company recognized as additional research and development expense $80.2 million and $72.6 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent®, sarilumab, and, commencing in the first quarter of 2016, Dupixent® (dupilumab).

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and, effective in the first quarter of 2016, Dupixent.

During the nine months ended September 30, 2015, the Company and Sanofi shared commercialization expenses, including those incurred by Sanofi, related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In July 2015, the U.S. Food and Drug Administration ("FDA") approved Praluent in the United States and in September 2015, the European Commission granted marketing authorization of Praluent. Therefore, commencing in the third quarter of 2015, the Company also recorded within Sanofi collaboration revenue its share of the Antibody Collaboration's losses in connection with commercialization of Praluent. In addition, effective in the first quarter of 2016, the Company and Sanofi also began sharing pre-launch commercialization expenses related to Dupixent. As such, during the three and nine months ended September 30, 2016, the Company recorded its share of losses in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and Dupixent within Sanofi collaboration revenue.

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 $150.0 million in 2016 to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. 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 ("REGN2810"). The parties share equally, on an ongoing basis, development expenses for REGN2810.

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.

ZALTRAP

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"). Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP during each calendar year.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015, the Company recognized $14.9 million of collaboration revenue, which was previously recorded as deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since the risk of inventory loss no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as the Company had no further performance obligations. In addition, during the three months ended September 30, 2016 and 2015, the Company

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

recorded $6.7 million and $9.0 million, respectively, and during the nine months ended September 30, 2016 and 2015, the Company recorded $21.3 million and $32.0 million, respectively, in other revenue primarily related to a percentage of net sales of ZALTRAP and manufacturing ZALTRAP commercial supplies for Sanofi.

b. Bayer

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

	Three Months Ended September 30,	
Bayer Collaboration Revenue	**2016**	**2015**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 170,854	$ 130,510
Cost-sharing of Regeneron EYLEA development expenses	2,219	1,827
Other	6,077	21,155
Total EYLEA	179,150	153,492
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept (REGN2176-3) development expenses	3,912	1,508
Other	2,603	2,596
Total PDGFR-beta	6,515	4,104
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	3,521	—
Other	2,112	—
Total Ang2	5,633	—
	$ 191,298	$ 157,596

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

	Nine Months Ended September 30,	
Bayer Collaboration Revenue	**2016**	**2015**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 484,181	$ 326,567
Sales milestones	—	15,000
Cost-sharing of Regeneron EYLEA development expenses	7,186	6,948
Other	45,924	50,685
Total EYLEA	537,291	399,200
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept (REGN2176-3) development expenses	8,570	8,688
Other	7,836	7,791
Total PDGFR-beta antibody	16,406	16,479
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	5,595	—
Other	3,494	—
Total Ang2 antibody	9,089	—
	$ 562,786	$ 415,679

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, all agreed-upon EYLEA development costs incurred by the Company and Bayer are shared equally. In the first quarter of 2015, the Company earned a $15.0 million sales milestone from Bayer upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period, which was the final milestone payment under the agreement.

PDGFR-beta antibody outside the United States

In 2014, the Company entered into an 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 in combination with aflibercept, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States.

Ang2 antibody outside the United States

In March 2016, the Company entered into an agreement with Bayer governing the joint development and commercialization outside the United States of an antibody product candidate to angiopoietin-2 (Ang2), including in combination with aflibercept, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to the Company and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. The Company is also entitled to receive up to an aggregate of $80.0 million in development milestone payments from Bayer. Bayer will share profits and losses from sales outside the United States equally with the Company, and is responsible for certain royalties payable to Sanofi on sales of the product outside of the United States. Within the United States, the Company has exclusive commercialization rights and will retain all of the profits from sales.

At the inception of the agreement, the Company's significant deliverables consisted of (i) a license to certain rights and intellectual property, (ii) providing research and development services, and (iii) manufacturing clinical supplies. The Company concluded that the license did not have standalone value, as such right was not sold separately by the Company, nor could Bayer receive any benefit from the license without the fulfillment of other ongoing obligations by the Company, including the clinical supply arrangement. Therefore, the deliverables were considered a single unit of accounting. Consequently, the $50.0 million up-front payment was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing an Ang2 antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both the Company and Bayer.

c. Mitsubishi Tanabe Pharma

In September 2015, the Company and Mitsubishi Tanabe Pharma Corporation ("MTPC") entered into a collaboration agreement 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. In the first quarter of 2016, MTPC made additional payments of $45.0 million and $15.0 million to the Company, which were recorded as deferred revenue and will be recognized ratably as revenue over the same performance period as the up-front payment.

d. Teva

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

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

At the inception of the Teva Collaboration Agreement, the Company's significant deliverables consisted of (i) a license to certain rights and intellectual property, (ii) providing research and development services, and (iii) manufacturing clinical supplies. The Company concluded that the license did not have standalone value, primarily due to the fact that such rights were not sold separately by the Company, nor could Teva receive any benefit from the license without the fulfillment of the other ongoing obligations by the Company, including the clinical supply arrangement. Therefore, the deliverables were considered a single unit of accounting. Consequently, the $250.0 million up-front payment was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

e. Intellia Therapeutics

In April 2016, the Company entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas gene-editing technology for *in vivo* therapeutic development. The Company will collaborate with Intellia to conduct research for the discovery, development, and commercialization of new therapies ("Product Collaboration"), in addition to the research and technology development of the CRISPR/Cas platform ("Technology Collaboration"). In connection with the execution of the agreement, the Company made a $75.0 million up-front payment, which was recorded as research and development expense in the second quarter of 2016, and also agreed to purchase Intellia shares contingent upon Intellia consummating its next equity financing. The Company is responsible for costs of developing and commercializing CRISPR/Cas products under the Product Collaboration agreement and is also obligated to pay potential development and sales milestones, and royalties on any future sales of such products resulting from the development and commercialization of CRISPR/Cas products. In addition, under the Technology Collaboration agreement, the Company is responsible for funding certain research and technology development costs.

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

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

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

In May 2016, Intellia completed an initial public offering ("IPO") of its common stock and thereby triggered the Company's obligation to purchase up to $50.0 million of Intellia common stock in a concurrent private placement. As part of the concurrent private placement, the Company purchased from Intellia at the closing of the IPO 2,777,777 shares of Intellia common stock for an aggregate purchase price of $50.0 million (see Note 5).

f. Adicet Bio

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

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

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

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,	
	2016	**2015**
Net income - basic	$ 264,804	$ 210,398
Effect of dilutive securities:		
Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs	—	145
Net income - diluted	$ 264,804	$ 210,543
(Shares in thousands)		
Weighted average shares - basic	104,833	103,348
Effect of dilutive securities:		
Stock options	10,156	9,632
Restricted stock	479	481
Convertible senior notes	—	308
Warrants	998	2,175
Dilutive potential shares	11,633	12,596
Weighted average shares - diluted	116,466	115,944
Net income per share - basic	$ 2.53	$ 2.04
Net income per share - diluted	$ 2.27	$ 1.82

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

	Nine Months Ended September 30,	
	2016	**2015**
Net income - basic	$ 642,407	$ 481,062
Effect of dilutive securities:		
Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs	397	—
Net income - diluted	$ 642,804	$ 481,062
(Shares in thousands)		
Weighted average shares - basic	104,586	102,825
Effect of dilutive securities:		
Stock options	10,340	9,449
Restricted stock	474	475
Convertible senior notes	81	—
Warrants	1,086	2,395
Dilutive potential shares	11,981	12,319
Weighted average shares - diluted	116,567	115,144
Net income per share - basic	$ 6.14	$ 4.68
Net income per share - diluted	$ 5.51	$ 4.18

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,	
(Shares in thousands)	**2016**	**2015**
Stock options	7,687	594
Restricted stock	19	—
Convertible senior notes	3	—

	Nine Months Ended September 30,	
(Shares in thousands)	**2016**	**2015**
Stock options	7,842	3,388
Restricted stock	19	—
Convertible senior notes	—	1,253

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, 2016 and December 31, 2015 consist of both debt securities of investment grade issuers as well as equity securities. The Company also held restricted marketable securities as of September 30, 2016, consisting of the Company's investment in shares of Intellia common stock (see Note 3), which are subject to customary transfer restrictions until November 2016 under a lock-up agreement with the underwriters of Intellia's IPO.

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

	Amortized	Unrealized		Fair
As of September 30, 2016	**Cost Basis**	**Gains**	**Losses**	**Value**
Unrestricted				
Corporate bonds	$ 966,235	$ 2,247	$ (561)	$ 967,921
U.S. government and government agency obligations	115,917	219	(40)	116,096
Municipal bonds	10,205	21	(1)	10,225
Commercial paper	73,417	2	—	73,419
Certificates of deposit	36,056	—	—	36,056
Equity securities	17,005	8,624	(7,565)	18,064
	1,218,835	11,113	(8,167)	1,221,781
Restricted				
Equity Securities	50,000	—	(5,843)	44,157
	$ 1,268,835	$ 11,113	$ (14,010)	$ 1,265,938

As of December 31, 2015				
Unrestricted				
Corporate bonds	$ 770,092	$ 156	$ (2,565)	$ 767,683
U.S. government and government agency obligations	51,402	—	(193)	51,209
Municipal bonds	17,930	5	(11)	17,924
Equity securities	17,005	14,462	—	31,467
	$ 856,429	$ 14,623	$ (2,769)	$ 868,283

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of September 30, 2016 mature at various dates through September 2021. The fair values of debt security investments by contractual maturity consist of the following:

	September 30, 2016	December 31, 2015
Maturities within one year	$ 443,875	$ 236,121
Maturities after one year through five years	759,842	600,695
	$ 1,203,717	$ 836,816

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(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, 2016	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Unrestricted						
Corporate bonds	$ 354,112	$ (475)	$ 52,787	$ (86)	$ 406,899	$ (561)
U.S. government and government agency obligations	29,200	(40)	—	—	29,200	(40)
Municipal bonds	1,529	(1)	—	—	1,529	(1)
Equity securities	7,435	(7,565)	—	—	7,435	(7,565)
	392,276	(8,081)	52,787	(86)	445,063	(8,167)
Restricted						
Equity securities	44,157	(5,843)	—	—	44,157	(5,843)
	$ 436,433	$ (13,924)	$ 52,787	$ (86)	$ 489,220	$ (14,010)
As of December 31, 2015						
Corporate bonds	$ 668,199	$ (2,473)	$ 23,749	$ (92)	$ 691,948	$ (2,565)
U.S. government and government agency obligations	51,215	(193)	—	—	51,215	(193)
Municipal bonds	11,917	(11)	—	—	11,917	(11)
	$ 731,331	$ (2,677)	$ 23,749	$ (92)	$ 755,080	$ (2,769)

Realized gains and losses on sales of marketable securities were not material for the three and nine months ended September 30, 2016 and 2015.

Changes in the Company's accumulated other comprehensive income (loss) for the three and nine months ended September 30, 2016 and 2015 related to unrealized gains and losses on available-for-sale marketable securities. For the three and nine months ended September 30, 2016 and 2015, amounts reclassified from accumulated other comprehensive income (loss) into investment income in the Company's Statements of Operations were related to realized gains and losses on sales of marketable securities.

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

6. Fair Value Measurements

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

		Fair Value Measurements at Reporting Date Using	
As of September 30, 2016	**Fair Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$ 967,921	—	$ 967,921
U.S. government and government agency obligations	116,096	—	116,096
Municipal bonds	10,225	—	10,225
Commercial paper	73,419	—	73,419
Certificates of deposit	36,056	—	36,056
Equity securities	18,064	$ 18,064	—
	1,221,781	18,064	1,203,717
Restricted			
Equity securities	44,157	—	44,157
	$ 1,265,938	$ 18,064	$ 1,247,874
As of December 31, 2015			
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$ 767,683	—	$ 767,683
U.S. government and government agency obligations	51,209	—	51,209
Municipal bonds	17,924	—	17,924
Equity securities	31,467	$ 31,467	—
	$ 868,283	$ 31,467	$ 836,816

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and nine months ended September 30, 2016 and 2015.

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, 2016 and 2015. During the nine months ended September 30, 2015, transfers of marketable securities from Level 2 to Level 1 were $91.4 million in connection with the lapse of the transfer restrictions on the Company's investment in Adverum Biotechnologies, Inc. (formerly Avalanche Biotechnologies, Inc.) common shares in January 2015. The Company's policy for recognition of transfers between levels of the fair value hierarchy is to recognize any transfer at the beginning of the fiscal quarter in which the determination to transfer was made. There were no other transfers of marketable securities between Levels 1, 2, or 3 classifications during the nine months ended September 30, 2016 and 2015. The

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

Company's investment in Intellia common stock was classified as a Level 2 marketable security as of September 30, 2016 (see Note 5).

As of September 30, 2016 and December 31, 2015, the Company had $0.2 million and $11.2 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") outstanding that matured in October 2016 (see Note 9). The fair value of the outstanding Notes was estimated to be $72.8 million as of December 31, 2015, and was determined based on Level 2 inputs, such as market and observable sources. The fair value of the outstanding Notes as of September 30, 2016 was not material.

7. Inventories

Inventories consist of the following:

	September 30, 2016	December 31, 2015
Raw materials	$ 89,675	$ 59,151
Work-in-process	164,062	132,068
Finished goods	16,980	11,197
Deferred costs	74,903	36,162
	$ 345,620	$ 238,578

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the three months ended September 30, 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $5.0 million and $1.8 million, respectively. For the nine months ended September 30, 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $11.3 million and $9.9 million, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2016	December 31, 2015
Accounts payable	$ 124,497	$ 140,962
Accrued payroll and related costs	139,722	133,223
Accrued clinical trial expense	82,269	88,297
Accrued sales-related charges, deductions, and royalties	129,485	195,986
Income taxes payable	155,485	—
Other accrued expenses and liabilities	83,458	85,644
	$ 714,916	$ 644,112

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 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 stockholder's 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.

The aggregate principal amount of Notes that remained outstanding as of September 30, 2016 was $0.2 million, which subsequently matured in October 2016.

In the first nine months of 2015, the Company settled conversion obligations for $146.0 million principal amount of the Company's Notes. Upon settlement of the Notes, the Company paid $146.0 million in cash and issued 1,419,287 shares of Common Stock. In addition, in the first nine months of 2015, the Company allocated $705.9 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholder's equity. In addition, the Company recognized a $16.9 million loss during the first nine months of 2015 on the debt extinguishment. In connection with the Note conversions in the first nine months of 2015, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 1,419,268 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 $119.2 million, as Treasury Stock during the first nine months of 2015.

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 (which was the remaining maximum number of warrants to be reduced subject to the amendment agreement).

In February 2016, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 975,142. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder closed out its hedge position, 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 half 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.

As of September 30, 2016, an aggregate of 1,345,027 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. The Company was obligated to settle any payments due under the amendment agreement in February 2015. Given that the amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the warrants subject to the agreement from additional paid-in capital to a liability in November 2014, with such liability subsequently measured at fair value with changes in fair value recognized in earnings. In February 2015, the Company paid a total of $124.0 million to reduce the number of warrants held by such warrant holder by 416,480. Upon expiration of the November 2014 amended agreement, in the first quarter of 2015 the remaining warrants were re-measured at fair value, and $23.3 million was reclassified back to additional paid-in capital, consistent with the original classification of the warrants under the 2011 issuance. Total losses related to changes in fair value of the warrants during the first quarter of 2015 were not material.

In addition to the November 2014 warrant transaction described above, during the first nine months of 2015, the Company entered into agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, the Company paid an aggregate amount of $399.5 million to the warrant holders during 2015 to reduce the number of shares of Common Stock issuable upon exercise of the warrant by 898,547 in the aggregate.

b. Credit Facility

In March 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, 2016, the Company had no borrowings outstanding under the credit facility and was in compliance with all credit facility covenants.

10. 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 $101.1 million and $182.9 million for the three months ended September 30, 2016 and 2015, respectively, and $345.9 million and $516.7 million for the nine months ended September 30, 2016 and 2015, respectively. The Company's effective tax rate was 27.6% and 46.5% for the three months ended September 30, 2016 and 2015, respectively, and 35.0% and 51.8% for the nine months ended September 30, 2016 and 2015, respectively. The Company's effective tax rate for the three and nine months ended September 30, 2016 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation (see Note 13), 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. 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's effective tax rate for the three and nine months ended September 30, 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

The Company also recorded an income tax benefit in its Statement of Comprehensive Income of $1.7 million and $6.5 million for the three months ended September 30, 2016 and 2015, respectively, and $3.3 million and $25.4 million for the nine months ended September 30, 2016 and 2015, respectively, primarily related to unrealized losses on available-for-sale marketable securities.

11. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

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. Included in accounts payable and accrued expenses as of September 30, 2015 and December 31, 2014 were $84.7 million and $56.2 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses as of December 31, 2014 was $7.5 million for the Company's conversion settlement obligation related to the Company's Notes which were surrendered for conversion but not settled as of December 31, 2014. The amount of such liability was not material as of September 30, 2016, September 30, 2015, and December 31, 2015.

Included in accounts payable and accrued expenses as of December 31, 2014 was $59.8 million related to the Company's payment obligation for a reduction in the number of warrants based on a warrant holder closing out a portion of its hedge position. Additionally, included within other current liabilities as of December 31, 2014 was $87.5 million in connection with the estimated fair value of the remaining warrant liability. There were no such liabilities recorded in connection with warrants as of September 30, 2016, December 31, 2015, and September 30, 2015.

The Company recognized an additional facility lease obligation of $16.4 million and $27.0 million during the nine months ended September 30, 2016 and 2015, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

12. Legal Matters

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

Proceedings Relating to '287 Patent, '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 altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings, the Company claims infringement of several claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable). At this time, the Company is not able to predict the outcome of, or estimate possible gain or a range of possible loss, if any, related to, these proceedings.

Proceedings Relating to Praluent (alirocumab) Injection

On October 17, 2014 and October 28, 2014, Amgen Inc. filed complaints against Regeneron, Sanofi, Aventisub LLC (subsequently removed and replaced with Sanofi-Aventis U.S. LLC), and Aventis Pharmaceuticals, Inc. in the United States District Court for the District of Delaware seeking an injunction to prohibit Regeneron and the other defendants from manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) Praluent, which Regeneron is jointly developing with Sanofi. On November 11, 2014 and November 17, 2014 Amgen filed complaints against Regeneron, Sanofi, Sanofi-Aventis U.S. LLC, and Aventis Pharmaceuticals, Inc. in the same court seeking the same relief. Amgen asserts U.S. Patent Nos. 8,563,698, 8,829,165 (the "'165 Patent"), and 8,859,741 (the "'741 Patent") in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 (the "'914 Patent") in the second complaint, U.S. Patent No. 8,883,983 in the third complaint, and U.S. Patent No. 8,889,834 in the fourth complaint. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. On December 15, 2014, all of the four proceedings were consolidated into a single case. On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint, which was granted on January 29, 2016. As amended, the complaint alleges, among other things, willful infringement of the asserted patents, which would allow the court to increase damages up to three times the amount assessed if the court finds willful infringement. On October 20, 2015, the District Court issued its claim construction order, in which it defined the meaning of certain disputed claim terms; none of the court's rulings were dispositive of the issues in the case. On November 3, 2015, pursuant to court order, the patents asserted by Amgen were narrowed to the '165, '741, and '914 Patents. On March 4, 2016, Amgen further narrowed the asserted patents to the '165 and '741 Patents.

A jury trial in this litigation was held from March 8 to March 16, 2016. During the course of the trial, the court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of Regeneron and Sanofi that there was no willful infringement of the asserted patent claims by Regeneron or Sanofi. 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 March 23 and March 24, 2016, the court held a permanent injunction hearing to determine whether Regeneron and Sanofi should be prohibited from commercializing Praluent. The parties to this litigation submitted post-trial briefs in the second quarter of 2016 and are awaiting the court's final opinion and judgment, including a decision on the permanent injunction. The Company and Sanofi plan to appeal any judgment or order that is adverse to the Company and Sanofi.

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 an injunction, damages, an accounting of profits, and costs and interest.

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 an injunction, an accounting of marketing activities, a recall of Praluent and its removal from distribution channels, and damages.

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

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

Proceedings Relating to Patents Owned by Genentech and City of Hope

On July 27, 2015, the Company and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Western Division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent (alirocumab), of U.S. Patent No. 7,923,221 (the "'221 Patent") jointly owned by Genentech, Inc. ("Genentech") and City of Hope relating to the production of recombinant antibodies by host cells. On the same day, the Company and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis") initiated an inter partes review in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of certain claims of U.S. Patent No. 6,331,415 (the "'415 Patent" and, together, with the "221 Patent", the "Cabilly Patents") jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies by host cells. On February 5, 2016, the USPTO instituted an inter partes review of the validity of most of the patent claims of the '415 Patent for which review had been requested. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by the Company and Sanofi concerning the '221 Patent in the District Court and counterclaimed, alleging that the Company and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On August 18, 2016, Regeneron and Sanofi-Aventis entered into a License and Settlement Agreement with Genentech and City of Hope that resolved all outstanding issues concerning the Cabilly Patents in the above-referenced litigation and inter partes review proceeding, resulting in a joint stipulation of dismissal being entered in the court and the USPTO. Under the agreement, Regeneron has been granted a license to the Cabilly Patents to make, use, and sell Praluent and all other antibody products under development at the time of the settlement.

Proceedings Relating to Shareholder Derivative Claims

On December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former non-employee members of the Company's board of directors, the Chairman of the board of directors, the Company's Chief Executive Officer, and the Company's Chief Scientific Officer as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2013 and 2014. The complaint seeks damages in favor of the Company for the alleged breaches of fiduciary duties and unjust enrichment; changes to Regeneron's corporate governance and internal procedures; invalidation of the 2014 Incentive Plan with respect to the individual defendants' compensation and a shareholder vote regarding the individual defendants' equity compensation; equitable relief, including an equitable accounting with disgorgement; and award of the costs of the action, including attorneys' fees. On March 2, 2016, the defendants filed a motion to dismiss the shareholder derivative complaint. On August 16, 2016, the court heard oral argument on defendants' motion to dismiss.

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

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

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

13. Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-09 ("ASU 2016-09"), *Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting*, which the Company elected to early adopt during the second quarter of 2016. ASU 2016-09 requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital). This aspect of ASU 2016-09 was adopted prospectively, and accordingly, the Company recorded excess tax benefits of $8.6 million and $64.1 million, respectively, within income tax expense for the three and nine months ended September 30, 2016, respectively. Included within income tax expense for the nine months ended September 30, 2016 is $15.6 million of excess tax benefits, which was previously recorded to additional paid-in capital during the first quarter of 2016. The amendments also require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Furthermore, the amendments require that excess tax benefits be classified as an operating activity in the statement of cash flows (such amounts were previously included as a financing activity in the statement of cash flows); the Company also adopted this provision of ASU 2016-09 prospectively.

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 ("lease liability") and a right-of-use asset representing its right to use the underlying asset for the lease term. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company is evaluating the impact that this guidance will have on the Company's financial statements.

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

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers*, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. In July 2015, the FASB decided to delay the effective date of the new standard by one year; as a result, the new standard will be effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption will be permitted, but no earlier than 2017 for calendar year-end entities. The standard allows for two transition methods - retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. The Company has not yet determined its method of transition and is evaluating the impact that this guidance will have on the Company's financial statements.

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, Praluent® (alirocumab) Injection, sarilumab, Dupixent® (dupilumab), fasinumab, and REGN2222; the likelihood and timing of achieving any of our anticipated clinical development milestones; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation EYLEA, Praluent, sarilumab, Dupixent, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; 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 and Bayer HealthCare LLC (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. 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 biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. We commercialize medicines for eye diseases, high low-density lipoprotein (LDL) cholesterol, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis (RA), asthma, atopic dermatitis, pain, cancer, and infectious diseases.

Our total revenues were $1,220.1 million in the third quarter and $3,633.6 million in the first nine months of 2016, compared to $1,137.4 million in the third quarter and $3,005.7 million in the first nine months of 2015. Our net income was $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, compared to net income of $210.4 million, or $1.82 per diluted share, in the third quarter and $481.1 million, or $4.18 per diluted share, in the first nine months of 2015. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

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

- **Praluent (alirocumab) Injection**, which is available in the United States where it is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol. Praluent is also available in certain countries in Europe for the treatment of adult patients with primary hypercholesterolemia (heterozygous familial hypercholesterolemia (HeFH) and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. In July 2016, the Japanese Ministry of Health, Labour and Welfare (MHLW) granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent.

- **ARCALYST® (rilonacept) Injection for Subcutaneous Use**, which is available in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 12 years and older.

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

Trap-based Clinical Program
EYLEA
In Phase 3 clinical development for the treatment of Neovascular Glaucoma (NVG) (in Japan) in collaboration with Bayer. Phase 3 study for the treatment of non-proliferative diabetic retinopathy (NPDR) in patients without DME initiated in the first quarter of 2016. As described below, aflibercept is also being studied in combination with (i) rinucumab, an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) nesvacumab, an antibody to angiopoietin-2 (Ang2).
Antibody-based Clinical Programs in Collaboration with Sanofi
Praluent
Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events.
Sarilumab (REGN88)
Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).
Dupixent (dupilumab/REGN668)
Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in adults (Phase 3), atopic dermatitis in pediatric patients (Phase 2), asthma (Phase 3), and eosinophilic esophagitis (EoE) (Phase 2). Plan to conduct Phase 3 studies in patients with nasal polyps.
REGN2810
Antibody to programmed cell death protein 1 (PD-1). In Phase 1 clinical development in solid tumors and advanced hematologic malignancies. Potentially pivotal Phase 2 study for the treatment of advanced cutaneous squamous cell carcinoma initiated in the second quarter of 2016. REGN 2810 is also being studied in combination with REGN1979 in B-cell malignancies.
REGN3500
Antibody to an undisclosed target being developed for inflammatory diseases. Phase 1 study in healthy volunteers initiated in the third quarter of 2016.
Antibody-based Clinical Program in Collaboration with Bayer
Rinucumab/aflibercept (REGN2176-3)**
Combination product comprised of an antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection for use in ophthalmology. The Phase 2 study in wet AMD did not meet its primary endpoint.
Nesvacumab/aflibercept (REGN910-3)**
Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 2 studies for the treatment of wet AMD and DME initiated in the first quarter of 2016. Fast track designation received from the FDA for the treatment of patients with wet AMD, DME, and diabetic retinopathy.

Antibody-based Clinical Program in Collaboration with Teva and Mitsubishi Tanabe Pharma
Fasinumab (REGN475)*
Antibody to Nerve Growth Factor (NGF). Phase 3 long-term safety and efficacy study in patients with osteoarthritis of knee and hip initiated in the first quarter of 2016. Phase 2b study for chronic low back pain initiated in the first quarter of 2016, and placed on clinical hold by the FDA in October 2016.
Antibody-based Clinical Programs Developing Independently
REGN2222*
Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. In Phase 3 clinical development for prevention of RSV infection.
Evinacumab (REGN1500)*
Antibody to Angptl-3. In Phase 1/2 clinical development for the treatment of homozygous familial hypercholesterolemia (HoFH) and severe forms of hyperlipidemia.
Trevogrumab (REGN1033)*
Antibody to myostatin (GDF8). Phase 2 monotherapy clinical development in skeletal muscle disorders completed. Combination therapy plans are in development.
REGN1908-1909*
Antibody to Feld1. In Phase 1 clinical development against allergic disease.
REGN1979
Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, and Acute Lymphoblastic Leukemia. REGN1979 is also being studied in combination with REGN2810 in B-cell malignancies.
REGN3470-3471-3479*
Antibody to Ebola virus. Phase 1 study in healthy volunteers initiated in the second quarter of 2016. Also in the second quarter of 2016, the FDA granted orphan-drug designation for the treatment of Ebola virus infection.
REGN2477*
Antibody to Activin A being developed for Fibrodysplasia Ossificans Progressiva (FOP). Phase 1 study in healthy volunteers initiated in the second quarter of 2016.

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

** Antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications, and antibodies targeting the Ang2 receptor and ligand in ophthalmology were previously included in our antibody collaboration with Sanofi. Under the terms of our agreements, Sanofi is entitled to receive potential development milestones and royalties on any future sales of the product candidates.

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

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

Marketed Products

EYLEA (aflibercept) Injection

We commenced sales of EYLEA in the United States for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, and DME and macular edema following RVO in 2014. In addition, in the first quarter of 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Outside the United States, Bayer commenced sales of EYLEA for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, and visual impairment due to DME and mCNV (in Japan) in 2014. In 2015, the European Commission and the Japanese Ministry of Health, Labour and Welfare (MHLW) approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. In addition, the European Commission approved EYLEA for the treatment of visual impairment due to mCNV in 2015. Bayer has additional regulatory applications for EYLEA for various indications pending in other countries, including EYLEA for the treatment of wet AMD in China.

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

Net product sales of EYLEA in the United States were $853.6 million in the third quarter and $2,465.4 million in the first nine months of 2016, compared to $734.4 million in the third quarter and $1,930.0 million in the first nine months of 2015. Bayer records net product sales of EYLEA outside the United States, which were $470.8 million in the third quarter and $1,375.9 million in the first nine months of 2016, compared to $371.1 million in the third quarter and $1,000.7 million in the first nine months of 2015.

Praluent (alirocumab) Injection

In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. 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. In July 2016, the Japanese Ministry of Health, Labour and Welfare (MHLW) granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk.

Under our antibody collaboration agreement, Sanofi records product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States and thus far have not exercised our option to co-promote Praluent outside the United States. We and Sanofi share profits and losses from sales of Praluent. Net product sales of Praluent in the United States were $31.6 million in the third quarter and $61.9 million in the first nine months of 2016, and net product sales of Praluent outside of the United States were $6.6 million in the third quarter and $13.8 million in the first nine months of 2016. Net product sales of Praluent were $4.0 million in both the third quarter and first nine months of 2015.

ARCALYST (rilonacept) Injection for Subcutaneous Use

ARCALYST is available in the United States for the treatment of CAPS in adults and children 12 years and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Net product sales of ARCALYST were $3.9 million in the third quarter and $10.5 million in the first nine months of 2016, compared to $3.2 million in the third quarter and $9.9 million in the first nine months of 2015.

Clinical Programs - Ophthalmologic Diseases

EYLEA - Ophthalmologic Diseases

Overview

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet AMD, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results. CRVO is caused by obstruction of the central retinal vein that leads to a back-up of blood and fluid in the retina. Release of VEGF contributes to increased vascular permeability in the eye and macular edema. In BRVO, a blockage occurs in the blood vessels branching from the main vein draining the retina, resulting in the release of VEGF and consequent retinal edema. For centrally involved DME, VEGF-mediated leakage of fluid from blood vessels in the eye results in interference with vision. Wet AMD, diabetic retinopathy (which includes DME), and RVO are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by neovascular proliferation and/or retinal edema.

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

Neovascular Glaucoma

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

NVG meets the criteria for an orphan indication in Japan where the estimated number of NVG patients is 30,000 to 40,000. In the second quarter of 2015, Bayer initiated a Phase 3 study in Japan to assess the efficacy and safety of intravitreal administration of aflibercept in comparison to sham treatment on the change in IOP in patients with NVG. The primary endpoint of this Phase 3 study (n=54), which was the change in IOP from baseline to week 1, was numerically in favor of EYLEA (p=0.06). Statistically significant improvements were observed in both neovascularization of the iris and neovascularization of the iridocorneal angle with EYLEA, compared to sham treatment. Most ocular treatment emergent adverse events were injection related, including conjunctival hemorrhage and injection site pain in the EYLEA group. Bayer expects to proceed with an Orphan Drug application with Japanese regulatory authorities.

Diabetic Retinopathy

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

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

Combination Product with Rinucumab

In September 2016, we announced top-line results from the Phase 2 CAPELLA study evaluating aflibercept co-formulated with rinucumab in patients with wet AMD. These data showed that at 12 weeks, the combination therapy did not add to the improvement in best corrected visual acuity (BCVA) that was demonstrated with intravitreal aflibercept injection monotherapy, the primary endpoint of the study. At 12 weeks, patients in both combination aflibercept/rinucumab groups showed a 5.8 letter improvement in BCVA. Patients treated with aflibercept alone showed a 7.5 letter improvement in BCVA. Results in the EYLEA monotherapy arm of this study were consistent with the efficacy and safety seen in Phase 3 pivotal studies of EYLEA in wet AMD. The efficacy results in the CAPELLA trial were consistent across all choroidal neovascularization subtypes. Adding rinucumab

to aflibercept showed no benefit on anatomic endpoints including reduction in retinal thickness or in resolution of subretinal hyper-reflective material. Ocular adverse events at 12 weeks were more common in the combination treatment groups (23.5% and 20%) compared to aflibercept alone (16%), primarily driven by an increase in conjunctival hemorrhage, eye irritation, and eye pain.

The 52-week portion of the Phase 2 CAPELLA study is currently ongoing.

Combination Product with Nesvacumab

In the first quarter of 2016, two Phase 2 studies, RUBY (for the treatment of DME) and ONYX (for the treatment of wet AMD), were initiated. Both studies are investigating nesvacumab, an antibody to Ang2 co-formulated with aflibercept, as a single, intravitreal injection.

Late-Stage Antibody-based Clinical Programs

Praluent for LDL cholesterol reduction

Overview

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

Clinical Programs

Phase 3 ODYSSEY Program. The global Phase 3 ODYSSEY program consists of more than 25,000 patients, and includes clinical trials evaluating the effect of Praluent on lowering LDL cholesterol. The potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial, which is fully enrolled and is expected to be completed in 2017. LDL cholesterol reduction is the primary efficacy endpoint for initial regulatory filings. The ODYSSEY program also includes two trials of Praluent dosed every four weeks, ODYSSEY CHOICE I and ODYSSEY CHOICE II. Patients in the ODYSSEY CHOICE I trial received Praluent 300 milligrams (mg) (most in combination with statins) every four weeks and patients in the CHOICE II trial received Praluent 150 mg monotherapy and in combination with non-statin lipid lowering therapy every four weeks.

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

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

- Ninety-three percent of patients treated with Praluent experienced at least a 50% reduction in their apheresis procedures ($p<0.0001$).
- Throughout the trial, patients treated with Praluent experienced significant reductions in their LDL cholesterol starting at week 6 (55% greater reduction compared to placebo), and lasting until the trial ended, at week 18 (46% greater reduction compared to placebo) ($p<0.0001$).
- A similar proportion of patients experienced adverse events (AEs) in both the Praluent and placebo groups (76% in both groups). The most common AEs (occurring in at least 5% of the Praluent group) were fatigue (15% Praluent; 10% placebo), nasopharyngitis (10% Praluent; 10% placebo), diarrhea (10% Praluent; 0% placebo), myalgia (10% Praluent; 5% placebo), upper respiratory infection (7% Praluent; 19% placebo), headache (7% Praluent; 5% placebo), arthralgia (7% Praluent; 10% placebo), and back pain (5% Praluent; 10% placebo).

In the first quarter of 2016, an independent Data Monitoring Committee (DMC) of the ODYSSEY OUTCOMES study completed the first interim analysis. In accordance with the protocol, the DMC performed a futility assessment. The DMC recommended the study continue with no changes. Regeneron remains blinded to the actual results of this analysis. An independent DMC will conduct a second interim analysis for futility and overwhelming efficacy (hazard ratio <0.802 corresponding to p<0.0001) for the primary endpoint with consistency across subgroups and regions, positive trends for secondary end points including all-cause mortality, and no excess non cardiovascular mortality. This second interim analysis is expected by the end of November 2016.

In the second quarter of 2016, the FDA accepted for review a supplemental BLA for a monthly dosing regimen of Praluent, with a target action date of January 24, 2017. In addition, a regulatory application for a monthly dosing regimen of Praluent was filed in the EU.

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

Sarilumab (REGN88; IL-6R Antibody) for inflammatory diseases

Overview

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

Rheumatoid Arthritis

Phase 3 Studies. We and Sanofi previously announced (and presented data) that in the 52 week SARIL-RA-MOBILITY Phase 3 clinical trial in adult patients with active RA who were inadequate responders to methotrexate (MTX) therapy, sarilumab treatment in combination with MTX improved disease signs and symptoms as well as physical function, and inhibited progression of joint damage. In addition, during 2015, we and Sanofi announced (and presented data) that in the 24 week SARIL-RA-TARGET Phase 3 clinical trial in adult patients with active RA who were inadequate responders or intolerant of TNF-alpha inhibitors, sarilumab treatment in combination with non-biologic disease modifying anti-rheumatic drugs (DMARD) therapy improved disease signs and symptoms, as well as physical function.

Two other Phase 3 studies, SARIL-RA-ASCERTAIN and SARIL-RA-EASY, also achieved their respective primary endpoints. SARIL-RA-ASCERTAIN was a patient safety calibrator study, designed to assess the safety of two subcutaneous doses of sarilumab and tocilizumab infusion in combination with DMARDs in patients with moderate-to-severe RA who were inadequate responders to or intolerant of TNF-alpha inhibitors. There were no clinically meaningful differences between the treatment groups in serious AEs and serious infections. SARIL-RA-EASY was designed to evaluate the technical performance and usability of the sarilumab autoinjector device. There were no product technical failures with the autoinjector, the primary endpoint of the study.

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

A BLA for U.S. regulatory approval of sarilumab was accepted for review by the FDA in December 2015, and the target date for an FDA decision on the BLA was October 30, 2016. However, on October 28, 2016, we and Sanofi announced that the FDA issued a Complete Response Letter (CRL) regarding the BLA for sarilumab. The CRL refers to certain deficiencies identified during a routine good manufacturing practice inspection of the Sanofi facility in Le Trait, France where sarilumab is filled and finished, one of the last steps in the manufacturing process. Satisfactory resolution of these deficiencies is required before the BLA can be approved. Sanofi submitted a comprehensive corrective action plan to the FDA, is implementing the corrective actions, and is working closely with the FDA towards a timely resolution. The CRL does not identify any concerns relating to the safety or efficacy of sarilumab. The sarilumab active pharmaceutical ingredient is manufactured by Regeneron at its Rensselaer, New York facility. The FDA has completed a pre-approval inspection of Regeneron's sarilumab manufacturing facility; no Form 483 was issued in connection with the pre-approval inspection of Regeneron's facility, which is the form used if the FDA investigators have observed any conditions that in their judgement may constitute a violation of the Food, Drug, and Cosmetic Act and related acts.

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

Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. SARIL-NIU-SATURN was a small Phase 2, randomized double-masked, placebo-controlled study (n=58) conducted to assess the effect of sarilumab on non-infectious uveitis of the posterior ocular segment. We reported results of this study at the pre-specified primary endpoint (week 16) during 2015. Top-line 52-week data were presented at the American Academy of Ophthalmology conference in October 2016.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

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

Dupixent (dupilumab/REGN668; IL-4R Antibody) for allergic and inflammatory conditions

Overview

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

Atopic Dermatitis

Phase 3 Study. The LIBERTY AD Phase 3 clinical program consists of five trials of patients with moderate-to-severe atopic dermatitis at sites worldwide. In 2015, three Phase 3 trials in atopic dermatitis, LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, and LIBERTY AD SOLO 2, completed enrollment. Patients from these studies were transitioned to either the ongoing LIBERTY CONTINUE or LIBERTY AD Open label Extension trials.

In 2014, the FDA granted Breakthrough Therapy designation to Dupixent for the treatment of adults with moderate-to-severe atopic dermatitis who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. This designation is based on positive results from Phase 1 and 2 clinical trials, the determination that atopic dermatitis is a serious disease, and preliminary clinical evidence that indicates that the drug may demonstrate substantial improvement over existing therapies. The FDA has accepted for priority review the BLA for Dupixent for the treatment of adult patients with inadequately controlled moderate-to-severe atopic dermatitis. The target date for an FDA decision on the BLA is March 29, 2017.

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

In April 2016, we and Sanofi announced positive top-line data from the Phase 3 LIBERTY AD SOLO 1 and SOLO 2 studies. These studies met their primary endpoints, and treatment with Dupixent as monotherapy significantly improved measures of overall disease severity, skin clearing, itching, quality of life, and mental health. A total of 1,379 adult patients with moderate-to-severe

atopic dermatitis were enrolled in the identically-designed SOLO 1 and SOLO 2 trials. Patients were enrolled if they were not adequately controlled with topical medications, or if topical treatment was not medically advisable. All patients were assessed via the 5-point Investigator's Global Assessment (IGA) scale, ranging from 0 (clear) to 4 (severe); entry criteria required a baseline score of 3 or 4. Patients were also assessed using the Eczema Area and Severity Index (EASI) and other measures. Patients were randomized into one of three treatment groups: Dupixent 300 mg subcutaneously once per week, Dupixent 300 mg subcutaneously every two weeks, or placebo for 16 weeks following an initial Dupixent loading dose of 600 mg subcutaneously, or placebo. Results at 16 weeks included the following:

- For SOLO 1 and SOLO 2, respectively, 37% and 36% of patients who received Dupixent 300 mg weekly, and 38% and 36% of patients who received Dupixent 300 mg every two weeks, achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 10% and 8.5% with placebo ($p<0.0001$). This was the primary endpoint of the study in the United States.
- For SOLO 1 and SOLO 2, respectively, the percent improvement in EASI from baseline was 72% and 69% in patients who received the 300 mg weekly dose, and 72% and 67% for patients who received Dupixent 300 mg every two weeks, compared to 38% and 31% for placebo ($p<0.0001$).
- For SOLO 1 and SOLO 2, respectively, 52.5% and 48% of patients who received Dupixent 300 mg weekly, and 51% and 44% of patients who received Dupixent 300 mg every two weeks, achieved EASI-75 compared to 15% and 12% with placebo ($p<0.0001$). This was the key secondary endpoint in the United States and one of the primary endpoints in the EU.

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

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

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

- 39% of patients who received either Dupixent 300 mg weekly with TCS or Dupixent 300 mg every two weeks with TCS achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 12% of patients receiving placebo with TCS ($p<0.0001$).
- 64% of patients who received Dupixent 300 mg weekly with TCS, and 69% of patients who received Dupixent 300 mg every two weeks with TCS achieved EASI-75, a 75% reduction on an index measuring eczema severity, compared to 23% of patients receiving placebo with TCS ($p<0.0001$).

The secondary endpoint 52-week results were the following:

- 40% of patients who received Dupixent 300 mg weekly with TCS, and 36% of patients who received Dupixent 300 mg every two weeks with TCS achieved clearing or near-clearing of skin lesions (IGA 0 or 1), compared to 12.5% of patients receiving placebo with TCS ($p<0.0001$).
- 64% of patients who received 300 mg weekly with TCS, and 65% of patients who received 300 mg every two weeks with TCS achieved EASI-75, compared to 22% with placebo with TCS ($p<0.0001$).

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

The overall rate of AEs in the LIBERTY AD CHRONOS study was comparable between the Dupixent with TCS groups (83% for the weekly dose (qw) and 88% for the every two weeks (q2w) dosing group) and the placebo with TCS group (84%). The rate of serious AEs was comparable between the Dupixent with TCS groups (3% (qw) and 4% (q2w)) and placebo with TCS group

(5%). Serious and/or severe infections were numerically higher in the placebo with TCS group (1% in both Dupixent groups and 2% placebo). Adverse events that were noted to have a higher rate with Dupixent included injection site reactions (20% (qw) and 16% (q2w) Dupixent; 9% placebo) and conjunctivitis (19% (qw) and 13% (q2w) Dupixent; 8% placebo); 22% of patients on placebo, and 23% (qw) and 28% (q2w) of patients on Dupixent reported a history of allergic conjunctivitis at study entry.

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

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

Asthma

Phase 3 Study. A Phase 3 trial, LIBERTY ASTHMA QUEST, in patients with uncontrolled persistent asthma was fully enrolled in the third quarter of 2016. LIBERTY ASTHMA QUEST is expected to serve as the second required pivotal efficacy study, since, based on discussions with the FDA, the Phase 2b study will also be considered a pivotal efficacy study. LIBERTY ASTHMA QUEST is a global, placebo-controlled Phase 3 study that enrolled more than 1,900 patients with uncontrolled persistent asthma and is evaluating two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

Nasal Polyps

Phase 3 Study. We and Sanofi plan to conduct Phase 3 studies in patients with nasal polyps.

Eosinophilic Esophagitis

Phase 2 Study. A Phase 2 trial of dupilumab in eosinophilic esophagitis was initiated in the first quarter of 2015 and is ongoing. EoE is a chronic allergic inflammatory disease that is considered a major cause of gastrointestinal illness. Eosinophils are a type of white blood cell that, due to allergens, can accumulate in the esophagus, causing inflammation and tissue injuries that create difficulty swallowing. People with eosinophilic esophagitis may also have allergies, asthma, atopic dermatitis, or chronic respiratory disease.

REGN2222 (RSV-F Antibody) for RSV

Overview

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

Clinical Program

A Phase 3 pivotal clinical study of REGN2222 (NURSERY Pre-Term) was initiated in 2015 and is currently enrolling patients.

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

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

Overview

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

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

Osteoarthritis

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

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

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

Chronic Low Back Pain

A Phase 2b study in chronic low back pain was initiated in the first quarter of 2016.

In October 2016, the FDA placed the Phase 2b study in chronic low back pain on clinical hold and requested an amendment of the study protocol after observing a case of adjudicated arthropathy in a patient receiving high dose fasinumab who had advanced osteoarthritis at study entry. We completed an unplanned interim review of results and stopped dosing in the study. The unplanned analysis showed clear evidence of efficacy with improvement in pain scores in all fasinumab groups compared to placebo at the 8- and 12-week time points (nominal $p<0.01$). Preliminary safety results are generally consistent with what has been previously reported with the class. The Phase 2b chronic low back pain study enrolled approximately 70% of the targeted 800 patients in four dose groups: placebo, 6mg subcutaneously monthly, 9mg subcutaneously monthly, and 9mg intravenously every two months. Patients will continue to be followed for up to 36 weeks.

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

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

Research Programs

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

In the first quarter of 2016, the *New England Journal of Medicine* published a paper based on the work done at the Regeneron Genetics Center showing that inactivating mutations of the angiopoeitin-like 4 (Angptl-4) gene are associated with a significantly reduced risk of coronary artery disease in humans. Angptl-3 and Angptl-4 are related genes that both regulate lipoprotein lipase.

Collaboration Agreements

Collaborations with Sanofi

Antibodies. Since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement (Antibody Discovery Agreement) and a License and Collaboration Agreement (each as amended), collectively referred to as the Antibody Collaboration. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi is responsible for funding up to $130.0 million of our antibody discovery activities in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. 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.

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

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. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. 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.

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

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). We have principal control over the development of REGN2810, and the parties share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any

other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

Collaborations with Bayer

EYLEA outside the United States. Since October 2006, we and Bayer have been parties to a license and collaboration agreement for the global development and commercialization outside the United States of EYLEA. Under the agreement, we and Bayer collaborate on, and share the costs of, the development of EYLEA through an integrated global plan. 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.

PDGFR-beta antibody outside the United States. In January 2014, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of rinucumab, an antibody product candidate to PDGFR-beta, including in combination with aflibercept, for the treatment of ocular diseases or disorders. Rinucumab/aflibercept, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept, is being developed under the agreement (see "Clinical Programs - Ophthalmologic Diseases" section above for the current status of development). Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer will have a right to opt-in to license and collaborate on further development and commercialization outside the United States. In connection with the agreement, Bayer is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, depending on whether Bayer opts-in to the collaboration, Bayer is obligated to reimburse us for either 25% or 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013.

If Bayer exercises its right to opt-in to the collaboration, they will obtain exclusive commercialization rights to the product outside the United States, continue to pay for 25% of global development costs and 50% of development costs exclusively for the territory outside the United States, pay a $20.0 million opt-in payment to us, pay a $20.0 million development milestone to us upon receipt of the first marketing approval in the EU or Japan, share profits and losses from sales outside the United States equally with us, and be responsible for the payment of royalties on sales outside the United States to Sanofi.

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

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing an Ang2 antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both us and Bayer.

Collaboration with Mitsubishi Tanabe Pharma

Fasinumab Asia. In September 2015, we entered into a collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) providing MTPC with development and commercial rights to fasinumab in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the MTPC Territories). In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment in 2015, and in the first quarter of 2016, MTPC made additional payments of $45.0 million and $15.0 million to us. We are also entitled to receive up to an aggregate of $155.0 million in development milestone and other contingent payments.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which

ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Collaboration with Teva

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

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

Collaboration with Intellia Therapeutics

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

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

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

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

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

Collaboration with Adicet Bio

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

Under the terms of the agreement, the parties will collaborate to identify and validate targets and work together to develop a pipeline of engineered immune-cell therapeutics for selected targets. We have the option to obtain development and commercial rights for a certain number of the product candidates developed by the parties, subject to an option payment for each product candidate. If we exercise our option on a given product candidate, Adicet then will have an option to participate in the development

and commercialization for such product. If Adicet doesn't exercise its option, Adicet will be entitled to royalties on any future sales of such products by us. In addition to developing CARs and TCRs for use in novel immune-cell therapies as part of the collaboration, we will have the right to use these CARs and TCRs in our other antibody programs outside of the collaboration.

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

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 Praluent and sarilumab and preparation for potential commercialization of Dupixent, approximately half of which we expect to be reimbursed by Sanofi under the companies' collaboration agreement. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, the continuation of our collaborations, in particular with Sanofi and Bayer, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators, and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2016 to date were, and plans for the next twelve months are, as follows:

Trap-based Clinical Program:

	2016 Events to Date	2016-2017 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 Initiated Phase 3 study for the treatment of NPDR in patients without DME Ÿ Reported positive top-line results from Phase 3 study in Japan for the treatment of NVG	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

Antibody-based Clinical Programs:

	2016 Events to Date	2016-2017 Plans (next 12 months)
Praluent (PCSK9 Antibody)	Ÿ Reported positive results from Phase 3 ODYSSEY ESCAPE trial Ÿ The DMC of the ODYSSEY OUTCOMES study completed the first interim analysis for futility and recommended the study continue with no changes Ÿ Supplemental BLA for monthly dosing regimen accepted for review by the FDA Ÿ Regulatory application filed for monthly dosing regimen in the EU Ÿ Japanese MHLW approved Praluent for the treatment of uncontrolled LDL cholesterol in certain adult patients	Ÿ Report additional data from Phase 3 ODYSSEY program Ÿ Submit for additional regulatory approvals outside the United States Ÿ Regulatory agency and reimbursement authority decisions on applications outside the United States Ÿ Prespecified early-stopping interim analysis by DMC of ODYSSEY OUTCOMES trial Ÿ FDA target action date of January 24, 2017 for monthly dosing regimen
Sarilumab (IL-6R Antibody)	Ÿ Reported positive top-line results from Phase 3 SARIL-RA-MONARCH trial Ÿ Regulatory applications submitted in the EU, Japan, and other jurisdictions outside the United States Ÿ Presented 52-week top-line data from Phase 2 SARIL-NIU-SATURN study at American Academy of Ophthalmology conference Ÿ FDA issued CRL regarding the BLA Ÿ Initiated Phase 2 study in pJIA	Ÿ Continue patient enrollment in Phase 3 SARIL-RA program Ÿ Sanofi to implement corrective actions pursuant to the CRL issued by the FDA Ÿ Submit for additional regulatory approvals outside the United States
Dupixent (dupilumab; IL-4R Antibody)	Ÿ Reported positive top-line results from Phase 3 LIBERTY AD SOLO 1 and SOLO 2 trials Ÿ Initiated Phase 3 LIBERTY AD CAFÉ study in atopic dermatitis Ÿ Reported positive results from Phase 3 LIBERTY AD CHRONOS study in atopic dermatitis Ÿ FDA accepted for priority review the BLA for atopic dermatitis Ÿ LIBERTY AD SOLO 1 and SOLO 2 results presented at EADV conference and simultaneously published in the *New England Journal of Medicine* Ÿ Completed patient enrollment in pivotal Phase 3 LIBERTY ASTHMA QUEST study Ÿ FDA granted Breakthrough Therapy designation for the treatment of atopic dermatitis in pediatric patients	Ÿ Submit for EU, Japan, and other regulatory approvals in atopic dermatitis outside the United States Ÿ Initiate Phase 3 studies in pediatric patients in atopic dermatitis and asthma Ÿ Initiate Phase 3 study in patients with nasal polyps Ÿ Complete patient enrollment in Phase 2 EoE study
REGN2222 (RSV-F Antibody)		Ÿ Complete patient enrollment in Phase 3 NURSERY Pre-Term study
Fasinumab (NGF Antibody)	Ÿ Initiated Phase 3 long-term safety and efficacy study in patients with osteoarthritis of knee or hip Ÿ Initiated Phase 2b study in chronic low back pain Ÿ Reported positive top-line results from Phase 2/3 study in patients with osteoarthritis pain Ÿ Phase 2b study in chronic low back pain put on clinical hold by FDA	Ÿ Continue patient enrollment in Phase 3 long-term safety and efficacy study in osteoarthritis Ÿ Report additional data from the Phase 2/3 study in patients with osteoarthritis pain Ÿ Initiate additional Phase 3 efficacy study in patients with osteoarthritis pain Ÿ Design pivotal Phase 3 study in chronic low back pain that excludes patients with advanced osteoarthritis

Antibody-based Clinical Programs (continued):

	2016 Events to Date	2016-2017 Plans (next 12 months)
Evinacumab (Angptl-3 Antibody)	Ÿ FDA granted orphan-drug designation for treatment of HoFH Ÿ Completed Phase 1 study in patients with dyslipidemia Ÿ Reported positive interim results from ongoing proof-of-concept study in patients with HoFH Ÿ Completed patient enrollment in Phase 2 HoFH study	Ÿ Report additional results from Phase 2 HoFH study
Rinucumab/aflibercept (PDGFR-beta Antibody co-formulated with aflibercept)	Ÿ Completed patient enrollment in Phase 2 study Ÿ Reported top-line results from Phase 2 study	Ÿ Report additional results from ongoing Phase 2 study
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	Ÿ Initiated Phase 2 studies in wet AMD and DME Ÿ Completed patient enrollment in Phase 2 RUBY study	Ÿ Continue patient enrollment in Phase 2 ONYX study
Trevogrumab (GDF8 Antibody)		Ÿ Initiate Phase 1 combination therapy studies with REGN2477
REGN2810 (PD-1 Antibody)	Ÿ Continued patient enrollment in Phase 1 study Ÿ Initiated Phase 2 potentially pivotal study for the treatment of advanced cutaneous squamous cell carcinoma Ÿ Initiated Phase 1 study in combination with REGN1979 for treatment of B-cell malignancies Ÿ Presented positive Phase 1 results from a dose-ranging study in heavily-pretreated patients with solid tumor cancers	Ÿ Continue patient enrollment in Phase 1 and Phase 2 studies Ÿ Initiate additional studies in additional indications
REGN1908-1909 (Feld1 Antibody)	Ÿ Completed initial proof-of-concept study	Ÿ Continue early stage development
REGN1979 (CD20 and CD3 Antibody)	Ÿ Continued patient enrollment in Phase 1 study Ÿ Initiated Phase 1 study in combination with REGN2810 for treatment of B-cell malignancies	Ÿ Complete patient enrollment in Phase 1 study
REGN3470-3471-3479 (Antibody to Ebola virus)	Ÿ Initiated Phase 1 study in healthy volunteers Ÿ FDA granted orphan-drug designation for the treatment of Ebola virus infection	Ÿ Continue patient enrollment in Phase 1 study
REGN2477 (Activin A Antibody)	Ÿ Initiated Phase 1 study in healthy volunteers Ÿ Completed patient enrollment in Phase 1 study in healthy volunteers	Ÿ Initiate Phase 1 study in patients
REGN3500 (target not disclosed)	Ÿ Initiated Phase 1 study in healthy volunteers	Ÿ Continue patient enrollment in Phase 1 study

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 Months Ended September 30, 2016 and 2015

Net Income

Net income for the three months ended September 30, 2016 and 2015 consists of the following:

(In millions)	**2016**	**2015**
Revenues	$ 1,220.1	$ 1,137.4
Operating expenses	(857.3)	(745.0)
Other income (expense)	3.1	0.9
Income before income taxes	365.9	393.3
Income tax expense	(101.1)	(182.9)
Net income	$ 264.8	$ 210.4

Revenues

Revenues for the three months ended September 30, 2016 and 2015 consist of the following:

(In millions)	**2016**	**2015**
Net product sales	$ 857.5	$ 737.6
Collaboration revenue:		
Sanofi	144.4	224.7
Bayer	191.3	157.6
Total collaboration revenue	335.7	382.3
Other revenue	26.9	17.5
Total revenues	$ 1,220.1	$ 1,137.4

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in 2014, macular edema following BRVO in 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended September 30, 2016, EYLEA net product sales increased to $853.6 million from $734.4 million for the three months ended September 30, 2015 due to higher sales volume. For the three months ended September 30, 2016 and 2015, we also recognized ARCALYST net product sales of $3.9 million and $3.2 million, respectively.

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 June 30, 2016	$ 11.6	$ 28.1	$ 1.1	$ 40.8
Provision related to current period sales	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
Balance as of June 30, 2015	$ 5.5	$ 39.5	$ 0.5	$ 45.5
Provision related to current period sales	15.8	33.3	2.6	51.7
Credits/payments	(14.9)	(34.6)	(2.6)	(52.1)
Balance as of September 30, 2015	$ 6.4	$ 38.2	$ 0.5	$ 45.1

Sanofi Collaboration Revenue

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

Sanofi Collaboration Revenue	Three Months Ended September 30,	
(In millions)	**2016**	**2015**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 131.4	$ 205.1
Reimbursement of Regeneron commercialization-related expenses	65.7	53.3
Regeneron's share of losses in connection with commercialization of antibodies	(112.0)	(74.9)
Other	3.1	2.6
Total Antibody	88.2	186.1
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	36.2	18.6
Other	20.0	20.0
Total Immuno-oncology	56.2	38.6
Total Sanofi collaboration revenue	$ 144.4	$ 224.7

In the third quarter of 2016, Sanofi's reimbursement of our antibody research and development expenses consisted of $24.4 million under our Antibody Discovery Agreement and $107.0 million under our License and Collaboration Agreement, compared to $42.5 million and $162.6 million, respectively, in the third quarter of 2015. Under the amended Antibody Discovery Agreement, Sanofi agreed to fund our antibody discovery activities up to $130.0 million in 2016 and up to $145.0 million in 2015. We earned lower reimbursement of our antibody discovery activities in the third quarter of 2016 because we reached Sanofi's maximum full-year funding level for these activities earlier in 2016 than in 2015. The lower reimbursement of research and development costs under our License and Collaboration Agreement in the third quarter of 2016, compared to the same period in 2015, was primarily due to decreased collaboration development activities for Praluent, sarilumab, and REGN2222. In 2016, Sanofi no longer co-develops and reimburses us for development activities for REGN2222.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and, effective in the first quarter of 2016, Dupixent.

During the three months ended September 30, 2015, we and Sanofi shared commercial expenses related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In July 2015, the FDA approved Praluent in

the United States and in September 2015, the European Commission granted marketing authorization of Praluent. Therefore, commencing in the third quarter of 2015, we also recorded within Sanofi collaboration revenue our share of the Antibody Collaboration's losses in connection with commercialization of Praluent. In addition, effective in the first quarter of 2016, we and Sanofi also began sharing pre-launch commercialization expenses related to Dupixent. As such, during the three months ended September 30, 2016, we recorded our share of losses in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and Dupixent within Sanofi collaboration revenue. Sanofi provides us with an estimate of our share of the losses from preparing to commercialize, or commercialization (as applicable), 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. Our share of losses in connection with commercialization of antibodies increased in the third quarter of 2016 compared to the third quarter of 2015 due to higher commercialization expenses in connection with the ongoing launch of Praluent, partly offset by higher Praluent product sales, and higher expenses in connection with preparing to commercialize sarilumab and Dupixent. Praluent net product sales, which are recorded by Sanofi, were $38.2 million and $4.0 million in the third quarter of 2016 and 2015, respectively.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology. In the third quarter of 2016, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $20.6 million under our IO Discovery Agreement and $15.6 million under our IO License and Collaboration Agreement related to REGN2810, compared to $12.8 million and $5.8 million, respectively, in the third quarter of 2015.

Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements. As of September 30, 2016, $540.0 million of the up-front payments was deferred and will be recognized ratably as revenue in future periods.

Bayer Collaboration Revenue

The collaboration revenue we earned from Bayer, as detailed below, primarily consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States.

Bayer Collaboration Revenue	**Three Months Ended September 30,**	
(In millions)	**2016**	**2015**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 170.9	$ 130.5
Cost-sharing of Regeneron EYLEA development expenses	2.2	1.8
Other	6.1	21.2
Total EYLEA	179.2	153.5
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept development expenses	3.9	1.5
Other	2.6	2.6
Total PDGFR-beta antibody	6.5	4.1
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept development expenses	3.5	—
Other	2.1	—
Total Ang2 antibody	5.6	—
Total Bayer collaboration revenue	$ 191.3	$ 157.6

Bayer commenced sales of EYLEA outside the United States for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME and mCNV (in Japan) in 2014, and macular edema following BRVO in the second quarter of 2015. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

Regeneron's Net Profit from EYLEA Sales Outside the United States	Three Months Ended September 30,	
(In millions)	**2016**	**2015**
Net product sales outside the United States	$ 470.8	$ 371.1
Regeneron's share of collaboration profit from sales outside the United States	184.4	144.2
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(13.5)	(13.7)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 170.9	$ 130.5

Bayer records revenue from sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profit or loss, 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. In the third quarter of 2016 and 2015, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer for a portion of the agreed-upon development expenses previously incurred by Bayer.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, including reimbursements for producing EYLEA commercial supplies for Bayer, and, in the third quarter of 2015, Bayer's share of royalties payable to Genentech pursuant to a license and settlement agreement (see "*Cost of Collaboration and Contract Manufacturing*" below for further details). In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer.

As described above under "Collaboration Agreements - Collaborations with Bayer - *Ang2 antibody outside the United States*," in March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. 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. As of September 30, 2016, $47.8 million of the up-front and other payments was deferred and will be recognized ratably as revenue in future periods.

Other Revenue

In connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the third quarter of both 2016 and 2015, we recognized $5.9 million of revenue related to this agreement.

In February 2015, we and Sanofi entered into an amended and restated ZALTRAP® agreement (Amended ZALTRAP Agreement). Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi also pays us a percentage of aggregate net sales of ZALTRAP. In connection with the Amended ZALTRAP Agreement, in the third quarter of 2016 and 2015, we recorded $6.7 million and $9.0 million, respectively, of revenue primarily related to (i) a percentage of net sales of ZALTRAP for the quarter that Sanofi is obligated to pay us and (ii) manufacturing ZALTRAP commercial supplies for Sanofi.

In connection with our fasinumab collaborations with MTPC and Teva, we recognized $9.6 million of other revenue in the third quarter of 2016. As described in the "Collaboration Agreements" section above, in late September 2015, we entered into a fasinumab collaboration agreement with MTPC, and, in September 2016, we entered into a fasinumab collaboration agreement with Teva.

Expenses

Total operating expenses increased to $857.3 million in the third quarter of 2016 from $745.0 million in the third quarter of 2015. Our average headcount in the third quarter of 2016 increased to 5,127 from 3,966 in the same period in 2015, principally in connection with expanding our research and development, manufacturing, and commercialization activities.

Operating expenses in the third quarter of 2016 and 2015 included a total of $131.4 million and $102.6 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the third quarter of 2016 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2015 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $543.0 million in the third quarter of 2016 from $425.9 million in the same period of 2015. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses	**Three Months Ended September 30,**		**Increase**
(In millions)	**2016**	**2015**	**(Decrease)**
Payroll and benefits [1]	$ 153.0	$ 129.2	$ 23.8
Clinical trial expenses	94.6	81.2	13.4
Clinical manufacturing costs [2]	155.7	121.0	34.7
Research and other development costs	67.5	33.4	34.1
Occupancy and other operating costs	44.2	33.5	10.7
Cost-sharing of Bayer and Sanofi development expenses [3]	28.0	27.6	0.4
Total research and development expenses	$ 543.0	$ 425.9	$ 117.1

[1] Includes Non-cash Compensation Expense of $67.5 million for the three months ended September 30, 2016 and $52.8 million for the three months ended September 30, 2015.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer, New York manufacturing facility. Also includes Non-cash Compensation Expense of $13.1 million for the three months ended September 30, 2016 and $10.8 million for the three months ended September 30, 2015.

[3] Under our collaborations with Bayer and Sanofi, in periods when Bayer or Sanofi incurs certain development expenses, we also recognize, as additional research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse. Our collaborators provide us with estimated development expenses for the most recent fiscal quarter. Bayer's and Sanofi's estimates are reconciled to their actual expenses for such quarter in the subsequent fiscal quarter, and our portion of our collaborators' development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased primarily due to (i) the initiation of additional clinical studies of fasinumab, (ii) additional enrollment in REGN2810 clinical studies as well as the 2016 initiation of a clinical study of REGN2810 for the treatment of advanced cutaneous squamous cell carcinoma, and (iii) the initiation of Phase 2 studies of nesvacumab/aflibercept in wet AMD and DME in 2016, partly offset by lower costs in connection with our Dupixent clinical program as some later-stage studies wind down. Clinical manufacturing costs increased primarily due to costs related to manufacturing additional drug supplies of Dupixent, fasinumab, REGN2810, and rinucumab/aflibercept, partly offset by manufacturing fewer clinical drug supplies of Praluent and sarilumab. Research and other development costs increased primarily due to the $25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet. Cost-sharing of Bayer and Sanofi development expenses includes our obligation to fund 20% of Sanofi's Phase 3 Dupixent development costs, which commenced during the first quarter of 2016.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer and Sanofi, the portion of Bayer's and Sanofi's respective development expenses which they incur and we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**Three Months Ended September 30,**		**Increase**
(In millions)	**2016**	**2015**	**(Decrease)**
Praluent	$ 36.8	$ 64.0	$ (27.2)
Dupixent	135.6	101.5	34.1
Sarilumab	9.4	29.2	(19.8)
Fasinumab	44.7	15.2	29.5
REGN2222	13.9	12.6	1.3
REGN2810	36.1	13.1	23.0
Other antibody candidates in clinical development	80.3	42.4	37.9
Other research programs and unallocated costs [(1)]	186.2	147.9	38.3
Total research and development expenses	$ 543.0	$ 425.9	$ 117.1

[(1)] For the three months ended September 30, 2016, includes the $25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet.

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

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 to $270.0 million in the third quarter of 2016 from $210.0 million in the third quarter of 2015 primarily due to (i) higher commercialization-related expenses associated with EYLEA and Praluent, (ii) higher contributions to not-for-profit organizations, including donations to independent not-for-profit patient assistance organizations, (iii) higher headcount and headcount-related costs, and (iv) higher Non-cash Compensation Expense principally for the reason described under "*Expenses*" above. Selling, general, and administrative expenses included $49.4 million and $36.5 million of Non-cash Compensation Expense in the third quarter of 2016 and 2015, respectively.

Cost of Goods Sold

Cost of goods sold decreased to $29.9 million in the third quarter of 2016 from $67.2 million in the third quarter of 2015. Cost of goods sold primarily consists of costs in connection with producing U.S. EYLEA commercial supplies, various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility, and royalties. Cost of goods sold decreased principally due to a decrease in royalties since our obligation to pay Genentech based on U.S. sales of EYLEA ended in May 2016.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer, decreased to $14.3 million in the third quarter of 2016 from $41.9 million in the third quarter of 2015. This decrease was primarily due to lower royalties since our obligation to pay Genentech based on sales of EYLEA outside the United States also ended in May 2016.

Income Taxes

In the third quarter of 2016 and 2015, we recorded income tax expense of $101.1 million and $182.9 million, respectively. The effective tax rate was 27.6% and 46.5% for the third quarter of 2016 and 2015, respectively. The third quarter 2016 effective tax rate was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, the federal tax credit for increased research activities, and changes to tax reserves, partly offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. As described in Note 13 of our Condensed Consolidated Financial Statements, we prospectively adopted Accounting Standards Update 2016-09 (ASU 2016-09), *Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting*, during the second quarter of 2016. ASU 2016-09 requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital).

The effective tax rate for the third quarter of 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-tax deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

Nine Months Ended September 30, 2016 and 2015

Net Income

Net income for the nine months ended September 30, 2016 and 2015 consists of the following:

(In millions)	2016	2015
Revenues	$ 3,633.6	$ 3,005.7
Operating expenses	(2,649.9)	(1,984.9)
Other income (expense)	4.6	(23.0)
Income before income taxes	988.3	997.8
Income tax expense	(345.9)	(516.7)
Net income	$ 642.4	$ 481.1

Revenues

Revenues for the nine months ended September 30, 2016 and 2015 consist of the following:

(In millions)	2016	2015
Net product sales	$ 2,475.9	$ 1,940.0
Collaboration revenue:		
Sanofi	527.5	593.2
Bayer	562.8	415.7
Total collaboration revenue	1,090.3	1,008.9
Other revenue	67.4	56.8
Total revenues	$ 3,633.6	$ 3,005.7

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. For the nine months ended September 30, 2016, EYLEA net product sales increased to $2,465.4 million from $1,930.0 million for the nine months ended September 30, 2015 due to higher sales volume. For the nine months ended September 30, 2016 and 2015, we also recognized ARCALYST net product sales of $10.5 million and $9.9 million, respectively.

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, 2015	$ 6.4	$ 48.3	$ 0.5	$ 55.2
Provision related to current period sales	63.5	113.8	22.8	200.1
Credits/payments	(62.5)	(135.5)	(19.5)	(217.5)
Balance as of September 30, 2016	$ 7.4	$ 26.6	$ 3.8	$ 37.8
Balance as of December 31, 2014	$ 3.1	$ 21.2	$ 0.5	$ 24.8
Provision related to current period sales	41.3	88.0	6.0	135.3
Credits/payments	(38.0)	(71.0)	(6.0)	(115.0)
Balance as of September 30, 2015	$ 6.4	$ 38.2	$ 0.5	$ 45.1

Sanofi Collaboration Revenue

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

Sanofi Collaboration Revenue	**Nine Months Ended September 30,**	
(In millions)	**2016**	**2015**
Antibody:		
Reimbursement of Regeneron research and development expenses	$ 469.2	$ 585.5
Reimbursement of Regeneron commercialization-related expenses	224.9	89.1
Regeneron's share of losses in connection with commercialization of antibodies	(333.5)	(143.6)
Other	9.0	7.7
Total Antibody	369.6	538.7
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	97.9	18.6
Other	60.0	20.0
Total Immuno-oncology	157.9	38.6
ZALTRAP:		
Reimbursement of Regeneron research and development expenses	—	0.7
Other	—	15.2
Total ZALTRAP	—	15.9
Total Sanofi collaboration revenue	$ 527.5	$ 593.2

In the first nine months of 2016, Sanofi's reimbursement of our antibody research and development expenses consisted of $130.0 million under our Antibody Discovery Agreement and $339.2 million under our License and Collaboration Agreement, compared to $145.0 million and $440.5 million, respectively, in the first nine months of 2015. Under the amended Antibody Discovery Agreement, Sanofi agreed to fund our antibody discovery activities up to $130.0 million in 2016 and up to $145.0 million in 2015. We earned lower reimbursement of our antibody discovery activities in the the first nine months of 2016 because we reached Sanofi's maximum full-year funding level for these activities earlier in 2016 than in 2015. The lower reimbursement of research and development costs under our License and Collaboration Agreement for the first nine months of 2016, compared to the same period in 2015, was primarily due to decreased development activities for Praluent and sarilumab, and the fact that in 2016, Sanofi no longer co-develops and reimburses us for development activities for REGN1033 and REGN2222. These decreases were partly offset by increased development activities for Dupixent.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and, effective in the first quarter of 2016, Dupixent.

During the nine months ended September 30, 2015, we and Sanofi shared commercial expenses related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. Commencing in the third quarter of 2015, after regulatory approval was received, we also recorded within Sanofi collaboration revenue our share of the Antibody Collaboration's losses in connection with commercialization of Praluent. In addition, effective in the first quarter of 2016, we and Sanofi also began sharing pre-launch commercialization expenses related to Dupixent. As such, during the nine months ended September 30, 2016, we recorded our share of losses in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and Dupixent within Sanofi collaboration revenue. Our share of losses in connection with commercialization of antibodies increased in the first nine months of 2016 compared to the first nine months of 2015 due to higher commercialization expenses in connection with the ongoing launch of Praluent, partly offset by higher Praluent product sales, and higher expenses in connection with preparing to commercialize sarilumab and Dupixent. Praluent net product sales, which are recorded by Sanofi, were $75.7 million and $4.0 million in the first nine months of 2016 and 2015, respectively.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology. In the first nine months of 2016, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $63.3 million under our IO Discovery Agreement and $34.6 million under our IO License and Collaboration Agreement related to REGN2810, compared to $12.8 million and $5.8 million, respectively, in the first nine months of 2015. Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015, we recognized $14.9 million of collaboration revenue, which was previously recorded as deferred revenue under the original ZALTRAP collaboration agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since our risk of inventory loss no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as we had no further performance obligations.

Bayer Collaboration Revenue

The collaboration revenue we earned from Bayer, as detailed below, primarily consisted of recognition of our share of profits in connection with commercialization of EYLEA outside the United States.

Bayer Collaboration Revenue	**Nine Months Ended September 30,**	
(In millions)	**2016**	**2015**
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 484.2	$ 326.6
Sales milestones	—	15.0
Cost-sharing of Regeneron EYLEA development expenses	7.2	6.9
Other	45.9	50.7
Total EYLEA	537.3	399.2
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept development expenses	8.6	8.7
Other	7.8	7.8
Total PDGFR-beta antibody	16.4	16.5
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept development expenses	5.6	—
Other	3.5	—
Total Ang2 antibody	9.1	—
Total Bayer collaboration revenue	$ 562.8	$ 415.7

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	Nine Months Ended September 30,	
(In millions)	2016	2015
Net product sales outside the United States	$ 1,375.9	$ 1,000.7
Regeneron's share of collaboration profit from sales outside the United States	524.8	368.1
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(40.6)	(41.5)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$ 484.2	$ 326.6

Bayer records revenue from sales of EYLEA outside the United States. In the first nine months of 2016 and 2015, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer for a portion of the agreed-upon development expenses previously incurred by Bayer.

In the first quarter of 2015, we earned our final $15.0 million sales milestone from Bayer, upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period.

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

Other Revenue

In connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first nine months of both 2016 and 2015, we recognized $17.7 million of revenue related to this agreement.

In connection with the Amended ZALTRAP Agreement, we recorded $21.3 million of revenue in the first nine months of 2016 primarily related to (i) a percentage of net sales of ZALTRAP for the quarter that Sanofi is obligated to pay us and (ii) manufacturing ZALTRAP commercial supplies for Sanofi. In the first nine months of 2015, we recorded $32.0 million of revenue in connection with the Amended ZALTRAP Agreement primarily related to (i) manufacturing ZALTRAP commercial supplies for Sanofi and (ii) a percentage of net sales of ZALTRAP from July 1, 2014 (the effective date of the Amended ZALTRAP Agreement) through September 30, 2015.

In connection with our fasinumab collaborations with MTPC and Teva, we recognized $17.1 million of other revenue in the first nine months of 2016. As described in the "Collaboration Agreements" section above, in late September 2015, we entered into a fasinumab collaboration agreement with MTPC, and, in September 2016, we entered into a fasinumab collaboration agreement with Teva.

Expenses

Total operating expenses increased to $2,649.9 million in the first nine months of 2016 from $1,984.8 million in the first nine months of 2015. Our average headcount in the first nine months of 2016 increased to 4,786 from 3,535 in the same period in 2015, principally in connection with expanding our research and development, manufacturing, and commercialization activities.

Operating expenses in the first nine months of 2016 and 2015 included a total of $405.3 million and $300.7 million, respectively, of Non-cash Compensation Expense. The increase in total Non-cash Compensation Expense in the first nine months of 2016 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2015 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $1,573.1 million in the first nine months of 2016 from $1,159.4 million in the same period of 2015. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses (In millions)	Nine Months Ended September 30, 2016	2015	Increase (Decrease)
Payroll and benefits [1]	$ 453.9	$ 365.9	$ 88.0
Clinical trial expenses	266.9	212.2	54.7
Clinical manufacturing costs [2]	419.9	306.0	113.9
Research and other development costs	220.7	98.6	122.1
Occupancy and other operating costs	130.0	97.6	32.4
Cost-sharing of Bayer and Sanofi development expenses [3]	81.7	79.1	2.6
Total research and development expenses	$ 1,573.1	$ 1,159.4	$ 413.7

[1] Includes Non-cash Compensation Expense of $200.5 million for the nine months ended September 30, 2016 and $154.2 million for the nine months ended September 30, 2015.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer, New York manufacturing facility. Also includes Non-cash Compensation Expense of $37.5 million for the nine months ended September 30, 2016 and $28.9 million for the nine months ended September 30, 2015.

[3] Under our collaborations with Bayer and Sanofi, in periods when Bayer or Sanofi incurs certain development expenses, we also recognize, as additional research and development expense, the portion of our collaborators' development expenses that we are obligated to reimburse.

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased primarily due to (i) the initiation of additional clinical studies of fasinumab, (ii) additional enrollment in REGN2810 clinical studies as well as the 2016 initiation of a clinical study of REGN2810 for the treatment of advanced cutaneous squamous cell carcinoma, and (iii) the initiation of Phase 2 studies of nesvacumab/aflibercept in wet AMD and DME in 2016, partly offset by lower costs in connection with our Dupixent clinical program as some later-stage studies wind down. Clinical manufacturing costs increased primarily due to higher costs related to purchases of higher volumes of clinical manufacturing supplies and manufacturing additional drug supplies of Dupixent, fasinumab, REGN2810, rinucumab/aflibercept, and REGN2222, partly offset by lower costs related to manufacturing fewer clinical supplies of Praluent and sarilumab. Research and other development costs increased primarily due to the $75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia, the $25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet, and an increase in lab supplies in connection with early stage research activities. Occupancy and other operating costs increased principally in connection with higher information technology- and facility-related costs at our Tarrytown and Rensselaer, New York sites due to higher headcount and expanded research and development activities.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer and Sanofi, the portion of Bayer's and Sanofi's respective development expenses which they incur and we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	**Nine Months Ended September 30,**		**Increase**
(In millions)	**2016**	**2015**	**(Decrease)**
Praluent	$ 118.8	$ 195.2	$ (76.4)
Dupixent	373.7	269.2	104.5
Sarilumab	36.7	67.4	(30.7)
Fasinumab	124.4	24.7	99.7
REGN2222	48.8	29.4	19.4
REGN2810	80.1	25.9	54.2
Other antibody candidates in clinical development	185.1	163.8	21.3
Other research programs and unallocated costs [(1)]	605.5	383.8	221.7
Total research and development expenses	$ 1,573.1	$ 1,159.4	$ 413.7

[(1)] For the nine months ended September 30, 2016, includes the $75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia and the $25.0 million up-front payment made in connection with the July 2016 license and collaboration agreement with Adicet.

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2016 and 2015, and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $851.8 million in the first nine months of 2016 from $543.6 million in the first nine months of 2015 primarily due to (i) higher commercialization-related expenses associated with EYLEA and Praluent, (ii) higher contributions to not-for-profit organizations, including donations to independent not-for-profit patient assistance organizations, (iii) higher headcount and headcount-related costs, and (iv) higher Non-cash Compensation Expense principally for the reason described under "*Expenses*" above. Selling, general, and administrative expenses included $157.2 million and $110.8 million of Non-cash Compensation Expense in the first nine months of 2016 and 2015, respectively.

Cost of Goods Sold

Cost of goods sold decreased to $150.1 million in the first nine months of 2016 from $170.6 million in the first nine months of 2015. Cost of goods sold primarily consists of costs in connection with producing U.S. EYLEA commercial supplies, various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility, and royalties. Cost of goods sold decreased principally due to the fact that, effective May 2016, we are no longer obligated to pay royalties to Genentech based on U.S. sales of EYLEA. This decrease was partly offset by an increase in Limerick start-up costs and an increase in U.S. EYLEA net sales. In addition, in the first nine months of 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $11.3 million and $9.9 million, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer, decreased to $74.9 million in the first nine months of 2016 from $111.3 million in the first nine months of 2015. This decrease was partly due to lower royalties since our obligation to pay Genentech based on sales of EYLEA outside the United States also ended in May 2016. In addition, in the first quarter of 2015, we recognized $20.2 million of expense for ZALTRAP commercial supplies that were previously shipped to Sanofi because our risk of inventory loss no longer existed under the Amended ZALTRAP Agreement.

Other Income and Expense

Interest and other expense in the first nine months of 2016 decreased compared to the first nine months of 2015 primarily due to (i) recognition of a $0.5 million and $16.9 million loss in the first nine months of 2016 and 2015, respectively, in connection with Notes which were surrendered for conversion during the respective periods, and (ii) a decrease in interest expense related to conversions of a substantial portion of the Notes in 2015.

Income Taxes

In the first nine months of 2016 and 2015, we recorded income tax expense of $345.9 million and $516.7 million, respectively. The effective tax rate was 35.0% and 51.8% for the first nine months of 2016 and 2015, respectively. The effective tax rate for the first nine months of 2016 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. However, the negative impact of those items was offset by the positive impact of the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, the federal tax credit for increased research activities.

The effective tax rate for the first nine months of 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-tax deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

Liquidity and Capital Resources

Sources and Uses of Cash for the Nine Months Ended September 30, 2016 and 2015

As of September 30, 2016, we had $2,186.3 million in cash, cash equivalents, and marketable securities compared with $1,677.4 million as of December 31, 2015. Additionally, as of September 30, 2016, we had borrowing availability of $750.0 million under a revolving credit facility that was entered into during the first quarter of 2015 (see further description under "*Credit Facility*" below).

Cash Provided by Operating Activities

Net cash provided by operating activities was $1,095.5 million in the first nine months of 2016. Our net income of $642.4 million in the first nine months of 2016 included Non-cash Compensation Expense of $405.3 million and depreciation and amortization of $75.8 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 share-based compensation, the tax basis of intangible assets, and deferred revenue.

As of September 30, 2016, Sanofi, Bayer, and trade accounts receivable increased by $176.1 million, compared to December 31, 2015, primarily due to higher U.S. EYLEA sales. Inventories as of September 30, 2016 increased by $99.7 million, compared to December 31, 2015, primarily due to increased production of commercial supplies of EYLEA and Praluent. 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 the companies' respective fasinumab collaborations, and the $50.0 million up-front payment from Bayer in connection with the companies' Ang2 collaboration (as described above), partly offset by the amortization of these 2016 payments and past 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.

Net cash provided by operating activities was $1,049.0 million in the first nine months of 2015. Our net income of $481.1 million in the first nine months of 2015 included Non-cash Compensation Expense of $300.7 million and depreciation and amortization of $52.0 million. In addition, deferred tax assets as of September 30, 2015 increased by $66.0 million, compared to December 31, 2014, primarily due to an increase in Non-cash Compensation Expense, partly offset by an increase in deferred tax liabilities associated with earnings of foreign subsidiaries.

As of September 30, 2015, Sanofi, Bayer, and trade accounts receivable increased by $462.9 million, compared to December 31, 2014, primarily due to higher U.S. EYLEA sales and higher amounts due from Sanofi in connection with the companies' Antibody Collaboration. Inventories as of September 30, 2015 increased by $66.3 million, compared to December 31, 2014, primarily due to increased production of EYLEA commercial supplies as well as capitalization of Praluent inventory. Deferred revenue increased by $624.1 million as of September 30, 2015, compared to December 31, 2014, primarily due to $640.0 million of up-front payments received from Sanofi in connection with the companies' IO Collaboration. Accounts payable, accrued expenses, and other liabilities increased by $164.7 million as of September 30, 2015, compared to December 31, 2014, primarily due to (i) higher accruals for sales-related charges and deductions, and royalties related to EYLEA, (ii) higher expenditures in connection with our expanding research and development activities, (iii) higher payroll and payroll-related costs, and (iv) higher tax-related liabilities.

Cash Used in Investing Activities

Net cash used in investing activities was $775.5 million and $784.3 million in the first nine months of 2016 and 2015, respectively. In the first nine months of 2016 and 2015, purchases of marketable securities exceeded sales or maturities by $414.1 million and $284.1 million, respectively. Capital expenditures were $361.5 million and $500.2 million in the first nine months of 2016 and 2015, respectively. 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 and additions 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 in the first nine months of 2015 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility, tenant improvement and associated costs related to two new buildings which were under construction at our leased Tarrytown, New York facilities, and expansion of our Rensselaer, New York manufacturing facilities. In addition, in April 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our current Tarrytown, New York Location for an aggregate purchase price of $73.0 million.

Cash Used in Financing Activities

Net cash used in financing activities was $208.7 million and $258.8 million in the first nine months of 2016 and 2015, respectively. In the first nine months of 2016 and 2015, $12.7 million and $146.0 million principal amount of our Notes, respectively, that was previously surrendered for conversion was settled. In accordance with the terms of the Notes, we elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of our Common Stock in respect of any amounts due in excess thereof. Also during the first nine months of 2016 and 2015, we paid an aggregate amount of $242.1 million and $523.5 million, respectively, to warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $89.8 million in the first nine months of 2016, compared to $150.4 million in the first nine months of 2015. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted stock (as applicable) were $47.0 million in the first nine months of 2016 compared to $71.7 million in the first nine months of 2015. In the first nine months of 2015, cash flows from financing activities included $305.6 million, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations. In the second quarter of 2016, we elected to adopt Accounting Standards Update 2016-09, *Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting*. As a result, we prospectively recorded excess tax benefits as an operating activity in the statement of cash flows (previously, such amounts were recognized as a financing activity in the statement of cash flows).

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, 2016.

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, 2016.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $361.5 million in the first nine months of 2016 and $500.2 million in the first nine months of 2015 (as described under "*Cash Used in Investing Activities*" above). We expect to incur capital expenditures of approximately $119 million to $149 million in the fourth quarter of 2016 primarily in connection with renovating our new Limerick, Ireland facility, expanding our Tarrytown, New York facilities, and expanding and renovating portions of our manufacturing facilities at our Rensselaer, New York facility.

Funding Requirements

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 testing). Clinical trial costs are dependent, among other things, on the size and duration of trials (for example, we have several ongoing late-stage clinical trials which are large and for which we expect to incur significant costs), fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. In addition to our anticipated commercialization costs for EYLEA and Praluent, we anticipate incurring substantial commercialization costs in connection with our late-stage antibody product candidates, including sarilumab and Dupixent. Commercialization costs over the next few years will depend on, among other things, whether or not our antibody product candidates in later stage clinical development receive regulatory approval, the market potential for product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby commercialization costs may be shared with our collaborators).

Under our collaborations with Sanofi and Bayer, we and our collaborator share profits and losses in connection with commercialization of drug products. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements. Currently, we are required to pay royalties on sales of certain commercial products. Under the provisions of the federal Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act of 2010, the Branded Prescription Drug Fee is imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. This fee is allocated to companies, including us, based on their market share of total branded prescription drug sales into these government programs.

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

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.

As of September 30, 2016, an aggregate of 1,345,027 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding. The warrants will become exercisable (and, if not exercised, will expire) at various dates during 2017. We may settle, at our option, any payments due under the warrant agreements in cash or shares of our Common Stock. We may also seek to further reduce the number of warrants outstanding prior to becoming exercisable through additional amendment agreements with warrant holders.

Future Impact of Recently Issued Accounting Standards

See Note 13 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 Around Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (filed February 11, 2016). There have been no material changes to our market risks or to our management of such risks as of September 30, 2016.

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, 2016 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, 2015 (filed February 11, 2016), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016 (filed May 5, 2016), our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016 (filed August 4, 2016), 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 and '163 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 European Patent No. 2,264,163 (the '163 Patent), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. A trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent was held from November 16, 2015 through December 8, 2015. On February 1, 2016, the court issued a final judgment, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. On April 27, 2016, the court granted permission for our appeal and Kymab's cross-appeal, and on May 18, 2016, Regeneron and Kymab filed their respective notices to appeal the court's decision on the '287 and '163 Patents. The hearing for the appeal and the cross-appeal is currently scheduled for October 2017.

On July 8 and July 13, 2016, notices of opposition against the '163 Patent were filed in the European Patent Office by Merus N.V. and Kymab and Novo Nordisk A/S, respectively. The notices assert, as applicable, lack of novelty, lack of inventive step, and insufficiency.

Proceedings Relating to Praluent (alirocumab) Injection

As previously reported, we are currently a party to a patent infringement action initiated by Amgen Inc. against us and Sanofi relating to Praluent, which we are jointly developing and commercializing with Sanofi. In this action, Amgen 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).

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

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

On September 26, 2016, Amgen filed a lawsuit for infringement of the '124 Patent in the Tribunal de grande instance in Paris, France against us, Sanofi-Aventis Groupe S.A., and Sanofi Winthrop Industrie. Amgen is seeking the prohibition of allegedly

infringing activities with a €10,000 penalty per drug unit of Praluent produced in violation of the court order sought by Amgen; an appointment of an expert for the assessment of damages; disclosure of technical (including supply-chain) and accounting information to the expert and the court; provisional damages of €10.0 million (which would be awarded on an interim basis pending final determination); reimbursement of costs; publication of the ruling in three newspapers; and provisional enforcement of the decision to be issued, which would ensure enforcement of the decision (including any provisional damages) pending appeal. Amgen is not seeking a preliminary injunction in this proceeding at this time.

Proceedings Relating to Patents Owned by Genentech and City of Hope

As previously reported, on July 27, 2015, we and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Western Division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent, of U.S. Patent No. 7,923,221 (the '221 Patent) jointly owned by Genentech, Inc. and City of Hope relating to the production of recombinant antibodies by host cells. On August 18, 2016, we and Sanofi entered into a License and Settlement Agreement with Genentech and City of Hope that resolved all outstanding issues concerning the '221 Patent and U.S. Patent No. 6,331,415 (collectively, the Cabilly Patents) in the above-referenced litigation and the previously reported inter partes review proceeding in the United States Patent and Trademark Office (USPTO), resulting in a joint stipulation of dismissal being entered in the court and the USPTO. Under the agreement, Regeneron has been granted a license to the Cabilly Patents to make, use, and sell Praluent and all other antibody products under development at the time of the settlement.

Proceedings Relating to Shareholder Derivative Claim

As previously reported, on December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former non-employee members of our board of directors, the Chairman of the board of directors, our Chief Executive Officer, and our Chief Scientific Officer as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties and were unjustly enriched when they approved and/or received allegedly excessive compensation in 2013 and 2014. On March 2, 2016, the defendants filed a motion to dismiss the shareholder derivative complaint. On August 16, 2016, the court heard oral argument on defendants' motion to dismiss. Pursuant to our By-Laws and the New York Business Corporation Law, expenses in connection with the foregoing are being advanced by us for the individual defendants.

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, 2016 and 2015, EYLEA net sales in the United States represented 68% and 64% 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;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices; and
- risks associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below.

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

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

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

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

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

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

Our sales in the United States of EYLEA are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in large part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. For example, in September 2011 the Office of Inspector General (OIG) of the Department of Health and Human Services issued a report entitled "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration" in which the OIG details possible savings to the Medicare program by using off-label, repackaged Avastin rather than Lucentis for the treatment of wet AMD. In addition, in March 2016, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services released a proposed rule regarding a new payment model for the reimbursement by Medicare of drugs administered in the physician office or hospital outpatient department settings. If approved, the proposed rule could potentially redistribute and reduce reimbursement currently available to physicians and hospitals that furnish such drugs, including EYLEA, and may also impact physician prescription practices. Economic pressure on state budgets may also have a similar impact. A reduction in the availability or extent of reimbursement from U.S. government programs could have a material adverse effect on the sales of EYLEA. In addition, other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. Since EYLEA is too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payers, including Medicare and Medicaid in the United States, is not available, our ability to successfully commercialize EYLEA will be materially adversely impacted. Our sales and potential profits and our business, prospects, operating results, and financial condition would be materially harmed. See also "Risks Related to Commercialization of Products - *The successful commercialization of our marketed products, as well as our late-stage product candidates or new indications for our marketed products, if approved, will depend on obtaining and maintaining coverage and reimbursement for use of these products from third-party payers, including Medicare and Medicaid in the United States, and these payers may not cover or adequately reimburse for use of our products or may do so at levels that make our products uncompetitive and/or unprofitable, which would materially harm our business, prospects, operating results, and financial condition*" below.

The commercial success of EYLEA is subject to strong competition.

The market for eye disease products is very competitive. 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 in patients with DME, and mCNV. Competitors are also exploring the development of a biosimilar version of Lucentis; in particular, Pfenex Inc. is developing PF582 (currently in a Phase 1b/2a trial in patients with wet AMD), and Formycon AG (in collaboration with bioeq GmbH) is developing FYB201 (currently in a Phase 3 trial in patients with wet AMD).

Other competitive or potentially competitive products include Allergan plc's Ozurdex® (dexamethasone intravitreal implant) (approved by the FDA in June 2009 for the treatment of macular edema following RVO and in September 2014 for the treatment of DME) and Alimera Sciences' Iluvien® (fluocinolone acetonide intravitreal implant) (approved by the FDA in September 2014 for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids. Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, and RVO, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, Genentech/Roche is developing a Lucentis port delivery system implant (currently in a Phase 2 study in patients with wet AMD). Novartis is developing RTH258 (ESBA1008), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated a non-inferiority Phase 3 trial comparing RTH258 and EYLEA in December 2014. Allergan is developing abicipar pegol (an anti-VEGF-A DARPin®) for wet AMD and related conditions (currently studied in Phase 3 trials against Lucentis as a comparator drug). Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, PDGF). Ophthotech Corporation (in collaboration with Novartis) is developing Fovista®, an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In 2013, Ophthotech initiated Phase 3 trials in AMD evaluating multiple combinations of Fovista, including Lucentis + Fovista, Avastin + Fovista, and EYLEA + Fovista. Genentech/Roche is developing a bi-specific antibody targeting both VEGF and Ang2 for wet AMD and DME (currently in Phase 2 trials for both indications). Competitors are also developing eye-drop formulations, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

In addition, ophthalmologists are using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, Avastin, for the treatment of wet AMD, DME, and RVO. The relatively low cost of therapy with repackaged Avastin in patients with wet AMD presents a significant competitive challenge in this indication. Competitors (including Amgen) are also developing a biosimilar version of Avastin. Long-term, controlled clinical trials comparing Lucentis to Avastin in the treatment of wet AMD are being conducted. One-year data from the Comparison of Age-Related Macular Degeneration Treatments Trial (CATT) were reported in April 2011 and indicated that Avastin dosed monthly was non-inferior to Lucentis dosed monthly in the primary efficacy endpoint of mean visual acuity gain at 52 weeks. Two-year data from CATT were reported in April 2012 and indicated that monthly Avastin was non-inferior to monthly Lucentis in mean visual acuity gain; as-needed dosing was *not* non-inferior to monthly dosing. Avastin is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other countries. Furthermore, Lucentis and off-label use of repackaged Avastin present significant competitive challenges as doctors and patients have had significant experience using these medicines. Moreover, the reported results of the CATT study, combined with the relatively low cost of repackaged Avastin in treating patients with wet AMD, may exacerbate the competitive challenge which EYLEA faces in this or other eye indications for which it is approved.

Finally, ZALTRAP has not been manufactured and formulated for use in intravitreal injections, and while we believe that ZALTRAP would not be well tolerated if administered directly to the eye, there is a risk that third parties may attempt to repackage ZALTRAP for off-label use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to EYLEA for its approved indications.

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

We rely on our collaboration with Bayer for commercializing EYLEA.

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

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

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

Our sales of EYLEA in the United States and Bayer's sales of EYLEA in other countries may be reduced if EYLEA is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. Prices for EYLEA in territories outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and our sales of EYLEA in the United States may be reduced if EYLEA marketed in those nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of EYLEA in a particular market or reduce our or Bayer's sales, thereby adversely affecting our results of operations. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues derived from EYLEA sales could be reduced.

Risks Related to Commercialization of Praluent

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

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

- effectiveness of the commercial strategy in and outside the United States for the marketing of Praluent, including pricing strategy and the effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- our and Sanofi's ability to differentiate Praluent from Amgen's Repatha® (evolocumab) and other competitive products;
- the ability of patients and providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- payer restrictions on eligible patient populations and the reimbursement process, both in the United States and abroad;
- our and Sanofi's ability to maintain sales of Praluent in the face of competitive products, including Repatha , as well as product candidates currently in clinical development;
- the results of post-approval studies of (i) Praluent (including the ongoing ODYSSEY OUTCOMES trial prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit), whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and (ii) other PCSK9 inhibitors, including Repatha, that could implicate an entire class of products or are perceived to do so;
- our ability to meet the demand for commercial supplies of Praluent;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices;
- maintaining and successfully monitoring commercial manufacturing arrangements for Praluent with third parties who perform fill/finish or other steps in the manufacture of Praluent to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities; and
- the outcome of the pending patent infringement proceedings initiated by Amgen against us and Sanofi (described further in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2015 and Part II, Item 1. "Legal Proceedings" of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2016 and June 30, 2016, respectively, and this report), and other risks associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below.

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

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

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

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

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

our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition" below.

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

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

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

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

The commercial success of Praluent is subject to strong competition.

There is significant actual and potential future competition for Praluent. Amgen's PCSK9 program is currently the most advanced of the competitors, having already received regulatory approvals in jurisdictions including the U.S., the EU, and Japan for its PCSK9 inhibitor Repatha. Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Several other companies, including AstraZeneca PLC and Eli Lilly and Company, also have development programs for antibodies against PCSK9. Alnylam Pharmaceuticals, Inc, in collaboration with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including oral products and vaccines. Oral products that lower LDL-C, if approved, may also be competitive with PCSK9 inhibitors, including Praluent. Certain late-stage inhibitors of cholesterylester transfer protein (CETP), such as Merck &Co., Inc's anacetrapib, lower LDL-C and may be launched with supporting data from outcomes trials prior to the completion of our own outcomes trial for Praluent. Other oral agents for lowering LDL-C that may potentially compete with Praluent include ETC-1002, which is being developed by Esperion Therapeutics, Inc.; and gemcabene, which is being developed by Gemphire Therapeutics Inc.

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

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

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

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

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

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

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

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

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the

data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. Its ability to do so has been enhanced by the Food and Drug Administration Amendments Act of 2007, pursuant to which the FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. Standard review can be accomplished in a ten-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within 6 months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending. Even if any of our applications receives a priority review designation, we may not ultimately be able to obtain approval of our application within a time frame consistent with the FDA's stated review goals or at all, and such designation may not actually lead to a faster development or regulatory review or approval process.

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

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

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

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

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

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

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness, and clinical trials evaluating our product candidates failed to meet the relevant endpoints. For example, in September 2016, we reported that in the Phase 2 study evaluating aflibercept co-formulated with rinucumab, an anti-platelet-derived growth factor receptor beta (anti-PDGFR-beta) antibody, in patients with wet AMD, the combination therapy did not demonstrate an improvement in best corrected visual acuity compared to intravitreal aflibercept injection monotherapy at 12 weeks. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property and Market Exclusivity

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 1,360,287 was, and our European Patent No. 2,264,163 is, the subject of opposition proceedings in the European Patent Office, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2015 and in Part II, Item 1. "Legal Proceedings" of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2016 and June 30, 2016, respectively, and this report (as applicable). We have pending patent applications in the United States Patent and Trademark Office, the European Patent Office, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review or inter partes reexamination under the America Invents Act of 2011 or ex parte reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune* technology, or any other of our technologies, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving our patents. For example, we are currently parties to patent infringement proceedings initiated by us relating to our European Patent No. 1,360,287, our European Patent No. 2,264,163, and our U.S. Patent No. 8,502,018, all of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2015 and Part II, Item 1. "Legal Proceedings" of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2016 and June 30, 2016, respectively, and this report. In addition, we are currently parties to patent infringement proceedings initiated by Amgen against us and Sanofi relating to Praluent, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2015 and Part II, Item 1. "Legal Proceedings" of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2016 and June 30, 2016, respectively, and this report. We are aware of additional patents and pending applications owned by others that claim antibodies to PCSK9 and methods of treating hypercholesterolemia with such antibodies. We are also aware of patents and pending applications owned by others that respectively claim antibodies to IL-6R and IL-4R and methods of treating rheumatoid arthritis and uveitis and atopic dermatitis and asthma with such antibodies. In addition to Praluent, our late-stage antibody-based pipeline includes sarilumab, an antibody to IL-6R, intended for the treatment of rheumatoid arthritis and non-infectious uveitis; Dupixent (dupilumab), an antibody to IL-4R, intended for the treatment of atopic dermatitis, asthma, nasal polyposis, and eosinophilic esophagitis; REGN2222, an antibody targeting RSV-F; and fasinumab, an antibody to NGF. Although we do not believe that any of our late-stage antibody product candidates infringes any valid claim in these patents or patent applications, these other parties could initiate lawsuits for patent infringement and assert that their patents are valid and cover our late-stage antibody product candidates, similar to the patent infringement proceedings initiated by Amgen referred to above. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our product candidates infringe such patents.

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

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

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

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

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "*If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed*," the scope and enforceability of our patent rights may

vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

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

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

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

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

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

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

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

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

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

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

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

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

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

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

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

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

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

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facility in Rensselaer, New York, including EYLEA, Praluent, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. For example, on October 28, 2016, the FDA issued a complete response letter relating to the BLA for sarilumab, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi facility in Le Trait, France where sarilumab is filled and finished; satisfactory resolution of these deficiencies is required before the BLA can be approved. While Sanofi submitted a comprehensive corrective action plan to the FDA and is implementing the corrective actions specified in that plan, there is no guarantee that Sanofi will be able to resolve those deficiencies timely or at all. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Risks Related to Commercialization of Products

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

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

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

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

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

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

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

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

There is also significant actual and potential future competition for Praluent, the PCSK9 antibody we are developing and commercializing in collaboration with Sanofi, as described in greater detail above under "Risks Related to Commercialization of Praluent - *The commercial success of Praluent is subject to strong competition*."

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

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody product candidate against NGF. Genentech/Roche is marketing an antibody against IL-6R (Actemra® (tocilizumab)) for the treatment of rheumatoid arthritis that would compete with sarilumab, our IL-6R antibody, if it is approved. In addition, several other companies, including Johnson & Johnson (in collaboration with GlaxoSmithKline plc), Alder Biopharmaceuticals, Inc., Ablynx (in collaboration with AbbVie), and R-Pharm, have antibodies against IL-6 or IL-6R in clinical development. A number of companies are developing antibodies that, if approved, may compete with Dupixent, our IL-4R antibody, if it is approved, including Roche (an antibody against IL-13), AstraZeneca (antibodies against IL-4R, IL-5R, and IL-13), Novartis (a combination antibody against IL-4 and IL-13), and Amgen (in collaboration with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). GlaxoSmithKline's Nucala® (mepolizumab) and Teva's Cinqair® (reslizumab), both of which are antibodies against IL-5, may also compete with Dupixent, if Dupixent is approved. For RSV, AstraZeneca commercializes an RSV-F protein antibody Synagis® (palivizumab), and other antibodies are in clinical development, including by AstraZeneca (in collaboration with AIMM Therapeutics).

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

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

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

In addition, in order for private insurance and governmental payers (such as Medicare and Medicaid in the United States) to reimburse the cost of our products, we must, among other things, maintain registration of the products in the National Drug Code registry, maintain our re-labeler license, maintain formulary approval by pharmacy benefits managers, and maintain recognition by insurance companies and CMS. There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage) of our current and future products, which may have a material adverse effect on our business.

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process (including by means of required prior authorizations and utilization management criteria). In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost-containment and other measures that are likely to adversely affect the amount of reimbursement for our current and future products. The full effects of this legislation depend on a number of factors, many of which are beyond our control, including new regulations and guidance issued by CMS and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

There is a risk that third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse our current and future products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement 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 nine months ended September 30, 2016, we recorded 99% of our total gross product revenue from sales to three distributors, and a single distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation, accounted for 56% of our total gross product revenue in the same period. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

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

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

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

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

Regulatory and Litigation Risks

If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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.

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

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

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

For example, on June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of the referendum, it is expected that the British government will begin negotiating the terms of the United Kingdom's future relationship with the EU. We do not know to what extent Brexit will impact the business and regulatory environment in the United Kingdom, the rest of the EU, or other countries. Changes impacting our ability to conduct business in the United Kingdom or other EU countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

We may incur additional tax liabilities related to our operations.

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

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

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with research institutions, including the Geisinger Health System, which are subject to such regulations. Regeneron is not currently classified as a covered entity or business associate under HIPAA and thus is not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators

in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs and research collaborations outside the U.S. implicate international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it. Our activities outside the U.S. impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our collaborators to comply with the strict rules on the transfer of personal data outside of the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

If Sanofi does not elect to co-develop the product candidates that we discover or opts out of their development under our Antibody Collaboration or our IO Collaboration, unless we enter into a collaboration agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, Sanofi has elected not to continue co-development of fasinumab, REGN2222, and trevogrumab, and decided not to opt in to the evinacumab and other programs.

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

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

We rely heavily on Bayer to assist with the development, and 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., President, Regeneron Laboratories and our Chief Scientific Officer; and Neil Stahl, Ph.D., our Executive Vice President, Research and Development. As we continue to commercialize EYLEA and Praluent and begin to commercialize other products assuming the receipt of required regulatory approvals, we are also highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

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

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may provide access to our confidential information to such third parties and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Such disruptions and breaches of security could result in legal proceedings, liability under laws that protect the privacy of personal information, disruptions to our operations, and damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing

If we cannot sustain profitability, our business, prospects, operating results, and financial condition would be materially harmed.

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

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

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the commercialization of EYLEA and Praluent and the anticipated commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody product candidates we are developing on our own (without a collaborator), and expenses for which we are responsible in accordance with the terms of our collaboration agreements.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable terms or at all. Our ability to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our late-stage product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of EYLEA, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

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

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

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

As of September 30, 2016, we had $920.4 million in cash and cash equivalents and $1,265.9 million in marketable securities (including $62.2 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

- fluctuations in our operating results, in particular net product sales of EYLEA;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA and Praluent;

- whether our net products sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management companies) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been maintaining its percentage ownership of our Common Stock and has 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, 2016, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 51.3% 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, 2016. As of September 30, 2016, Sanofi beneficially owned 23,418,396 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 may not be sold until the later of (i) December 20, 2020 and (ii) the expiration of our Antibody Discovery Agreement with Sanofi relating to our Antibody Collaboration (as amended) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In February 2013, we received from Sanofi a notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 that it intends to acquire additional Common Stock through open market purchases and direct purchases from shareholders. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase (subject to market conditions, including the price and availability of shares of our Common Stock, and legal and regulatory requirements) additional shares of our Common Stock to maintain and opportunistically increase its beneficial ownership on a percentage basis up to the maximum allowed under the "standstill" provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2016, holders of Class A Stock held 15.6% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2016:

- 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, 2016, and 21.6% 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, 2016; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 51.3% 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, 2016. In addition, these five shareholders plus our Chief Executive Officer held approximately 56.6% 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, 2016.

Pursuant to the January 2014 amended and restated investor agreement with us, Sanofi has agreed to vote its shares as recommended by our board of directors, except that it may elect to vote proportionally with the votes cast by all of our other shareholders with respect to certain change-of-control transactions and to vote in its sole discretion with respect to liquidation or dissolution of our company, stock issuances equal to or exceeding 20% of the then outstanding shares or voting rights of Common Stock and Class A Stock (taken together), and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

In addition, upon Sanofi reaching 20% ownership of our then outstanding shares of Class A Stock and Common Stock (taken together), we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition

of 20% of our then outstanding shares of Class A Stock and Common Stock (taken together) and (ii) 25% of our then outstanding shares of Class A Stock and Common Stock (taken together). This designee is required to be "independent" of our company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi. In April 2014, Sanofi notified us that it had reached the 20% ownership threshold and designated Robert A. Ingram as its designee. On April 4, 2014, following recommendation of the Corporate Governance and Compliance Committee, the board of directors elected Mr. Ingram as a director and a member of the Compensation Committee. Mr. Ingram was subsequently elected as a Class I director at our 2014 Annual Shareholder Meeting and resigned on November 10, 2015. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to designate a successor designee.

The warrant transactions we entered into in connection with our convertible senior notes issuance may affect the trading price of our Common Stock.

In connection with the issuance of our 1.875% convertible senior notes, which matured on October 1, 2016,we entered into warrant transactions with four financial institutions, or the warrant counterparties. The warrant transactions could have a dilutive effect from the issuance of Common Stock pursuant to the warrants. As of September 30, 2016, 1,345,027 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

In connection with hedging these transactions, the warrant counterparties and/or their affiliates may have entered into various derivative transactions with respect to our Common Stock, and may enter into, or may unwind, various derivative transactions and/or purchase or sell our Common Stock or other securities of ours in secondary market transactions. These activities could have the effect of increasing or preventing a decline in, or could have a negative effect on, the value of our Common Stock.

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

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

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- 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 then outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our company.

Similarly, under our 2014 PDGFR-beta license and collaboration agreement and our 2016 ANG2 license and collaboration agreement with Bayer, Bayer is prohibited from seeking to influence the control of our company or acquiring more than 20% of our then outstanding Class A Stock and Common Stock (taken together). With respect to each of these agreements, this prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement; (ii) the public announcement of a tender offer, exchange offer, or other proposal that would constitute a change of control of our company; (iii) the acquisition (other than by Dr. Schleifer or his affiliates) of more than 20% of the voting power of our then outstanding Class A Stock and Common Stock (taken together); (iv) the issuance of shares of capital stock to another party (other than to an underwriter in a public offering) that would result in such party's having more than 7% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such third party enters into a standstill agreement containing terms substantially similar to the standstill obligations of Bayer; 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 Pharmaceuticals International GmbH, 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 of more than 30% of the voting power of our then 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 then outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Teva; or (vi) other specified events, such as a liquidation or dissolution of our company.

In addition, upon the occurrence of certain extraordinary events, including certain mergers involving us, the warrant transactions we entered into in connection with the issuance of our Notes may be terminated, and the amounts we may be required to pay upon such termination could be significant. This may result in the acquisition of us being on terms less favorable to our shareholders than would otherwise be the case.

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our company. Also, stock options issued under our Second Amended and Restated 2000 Long-Term Incentive Plan and our 2014 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plans. Further, under the amended and restated investor agreement between us and Sanofi, we are required under certain circumstances to appoint an individual agreed upon by us and Sanofi to our board of directors and to use our reasonable efforts to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains a specified equity interest in us. As described above under "*Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval and over our management*," a Sanofi designee served on our board of directors from April 2014 to November 2015, and Sanofi has disclosed its intention to designate a successor designee. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

The following table reflects shares of Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted equity awards granted under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan or the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan in the third quarter of 2016.

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
9/1/2016-9/30/2016	4,943	$ 392.63	—	—

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number		Description
10.1	*	Collaboration Agreement, dated as of September 17, 2016, by and between Teva Pharmaceuticals International GmbH and Regeneron Ireland.
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

* Portions of this document have been omitted and filed separately with the Securities and Exchange Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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 4, 2016

By: /s/ Robert E. Landry

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

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets and asterisks [**********], have been separately filed with the Securities and Exchange Commission.

Exhibit 10.1

REDACTED

COLLABORATION AGREEMENT

By and Between

TEVA PHARMACEUTICALS INTERNATIONAL GmbH
and

REGENERON IRELAND

Dated as of September 17, 2016

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COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT ("Agreement"), dated as of September 17, 2016 (the "Effective Date"), is made by and between Teva Pharmaceuticals International GmbH, a Swiss limited liability company having a principal place of business at Schlüsselstrasse 12, 8645 Jona, Switzerland ("Teva"), and Regeneron Ireland, an Irish unlimited company having a principal place of business at Europa House, Block 9 Harcourt Street, Harcourt Street, Dublin 2, Ireland ("Regeneron") (with each of Teva and Regeneron being sometimes referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, Teva, Regeneron and their respective Affiliates possess knowledge and expertise in, and resources for, developing and commercializing biopharmaceutical products in the Field in the Territory (each as defined below);

WHEREAS, Regeneron is developing a biopharmaceutical product incorporating an anti-NGF antibody known as fasinumab, as further described herein;

WHEREAS, Regeneron wishes to grant to Teva, and Teva wishes to accept, certain rights to develop and commercialize such biopharmaceutical product in the Field in the Territory, as more fully described in this Agreement;

WHEREAS, Regeneron wishes to exclusively supply, and Teva wishes to have supplied exclusively by Regeneron, such biopharmaceutical product for Teva's exclusive distribution in the Ex-U.S. Territory (as defined below), as more fully described in this Agreement; and

WHEREAS, Teva and Regeneron desire to collaborate on such development and commercialization, as more fully described in this Agreement upon the terms and conditions set forth herein (the "Collaboration").

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Accounting Standards" shall mean, with respect to either Party, GAAP or IFRS, in each case, as generally and consistently applied throughout the Party's organization. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained.

1.2 "Acquired Competing Product" shall mean a Competing Product (other than the Product) the rights to which are acquired by a Party or one or more of its Affiliates through an acquisition (including by Change of Control), (a) by a Third Party of, or (b) of a Third Party or a business or division of a Third Party by, such Party or one or more of its Affiliates.

1.3 [**********]

1.4 "Additional Trial Costs" shall mean, with respect to any Additional Trial, [**********] in connection with the conduct of such Additional Trial and any Regulatory Filings made in connection therewith (including in connection with any Marketing Approvals).

1.5 "Additional Trial Plan" shall mean, with respect to an Additional Trial, the written plan for the conduct of such Additional Trial [**********], including a proposed budget for such Additional Trial, as each may be amended from time to time in accordance with the terms of this Agreement. For the avoidance of doubt, an "Additional Trial Plan" will not include Non-Approval Trials.

1.6 "Affiliate" shall mean, with respect to any Person, another Person that controls, is controlled by or is under common control with such first Person at any time for so long as such other Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, a Person shall be deemed to "control" another Person if such first Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to "control" another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the applicable Laws of certain countries outside of the United

States, the maximum percentage ownership permitted by applicable Law for a foreign investor may be equal to or less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence; *provided that* such foreign investor has the power to direct the management and policies of such entity.

1.7 "Ancillary Agreements" shall mean the Development Supply Agreement and the Commercial Supply Agreement.

1.8 "Antibody(ies)" shall mean a [**********].

1.9 "Anticipated First Commercial Sale" shall mean, with respect to the Product and, if the context specifies, with respect to one or more countries in the Territory, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale in such country(ies) in the Territory, if specified, or otherwise, in any country in the Territory.

1.10 "Approval" shall mean, with respect to a product (including the Product), any approval (including Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the development (including Development of the Product) or commercialization (including Commercialization of the Product) of such product in the Field in a regulatory jurisdiction in the Territory, and shall include, any approval, registration, license or authorization granted in connection with any Registration Filing. For clarity, a Marketing Approval is an Approval.

1.11 "Biosimilar Product" shall mean [**********].

1.12 "BLA" shall mean a biologics license application filed with respect to the Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

1.13 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States are authorized or required by applicable Law to remain closed.

1.14 [**********].

1.15 [**********].

1.16 "Calendar Year" shall mean each twelve (12) month period beginning on January 1st; *provided, however*, that (a) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year in which the Effective Date occurs and (b) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement expires and end on the expiration of the Term.

1.17 "Change of Control" shall mean, the Parent, with respect to Regeneron, or the ultimate parent entity of Teva, with respect to Teva (for purposes of this Agreement, such ultimate parent entity and the Parent are referred to each as "Controlling Parent"), any of the following events: (a) any Person is or becomes the "beneficial owner" (as such term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder (or, in each case, any successor thereto), except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all classes of capital stock then outstanding of Controlling Parent normally entitled to vote in elections of directors; (b) Controlling Parent consummates a merger, acquisition, consolidation or reorganization (or a series of such related transactions) involving Controlling Parent, other than (i) such transaction or transactions that would result in the voting securities of Controlling Parent outstanding immediately prior to such transaction or transactions continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the securities of Controlling Parent or such surviving entity or any parent thereof outstanding immediately after such transaction or transactions, or (ii) such transaction or transactions effected to implement a recapitalization of Controlling Parent (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of Controlling Parent representing a majority of the combined voting power of Parent's then outstanding securities; or (c) Controlling Parent conveys, transfers or leases all or substantially all of its assets to any Person other than a directly or indirectly wholly owned Affiliate of Controlling Parent.

1.18 [**********].

1.19 "Class A Stock" shall mean the Class A Stock of Parent, par value $0.001 per share.

1.20 "CMC Data" shall mean the chemistry, manufacturing and controls data for the Product required by applicable Law to be included or referenced in, or that otherwise supports, an IND or BLA.

1.21 "Co-Commercialize," "Co-Commercialization" or "Co-Commercializing" shall mean the joint Commercialization, including the Co-Promotion, of the Product by the Parties (or their respective Affiliates) under the same trademark in the United States pursuant to the U.S. Commercialization Plans.

1.22 "COGS" shall mean, with respect to a Quarter, Regeneron's or its Affiliate's Manufacturing Costs for (a) Product sold in the United States in such Quarter, excluding any Product Manufactured prior to the First Commercial Sale in the United States to the extent Regeneron's or

its Affiliate's cost with respect thereto was included as a Development Costs and (b) Product in inventory that is lost, destroyed, expired, spoiled, obsolete or otherwise written down in such Quarter [**********].

1.23 "Combination Product" shall mean:

(a) [**********]:

(b) [**********];

[**********].

1.24 "Commercial Supply Cost" shall mean, [**********], the Out-of-Pocket Cost for purchasing or the Manufacturing Cost for the Manufacture of Commercial Supply Requirements, including any filling, packaging, device manufacture and assembly, and labeling costs therefor, and any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.

1.25 "Commercial Supply Requirements" shall mean quantities of Finished Product as are required to fulfill requirements for commercial sales, Non-Approval Trials, charitable purposes, product sampling, promotional purposes, and other Commercialization uses with respect to the Product in the Field in the Territory.

1.26 "Commercialization Budget" shall mean the U.S. Commercialization Budget or Ex-U.S. Territory Commercialization Budget, as the context requires.

1.27 "Commercialization Plan" shall mean the U.S. Commercialization Plan or Ex-U.S. Territory Commercialization Plan, as the context requires.

1.28 "Commercialize," "Commercialization" or "Commercializing" shall mean any and all activities directed to marketing, promoting (including Co-Promoting), detailing, distributing, importing, offering for sale, having sold or selling the Product in the Field in the Territory and regulatory activities in support thereof (including maintaining Approvals), including market research, activities necessary to obtain or maintain Pricing Approvals, reimbursement or listing on health care providers' and payers' formularies, pre-launch marketing, marketing and educational activities, post-Approval pharmacovigilance excluding pharmacovigilance for clinical trials other than Non-Approval Trials, sampling and Non-Approval Trials in the Territory; [**********]. For clarity, the terms "Commercialize," "Commercialization" and "Commercializing" are used herein with respect to the Product while the terms "commercialize," "commercialization" and "commercializing" are used herein with corresponding meanings with respect to other products.

1.29 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts that a global biopharmaceutical company would normally devote to products or research or development projects of similar scientific and commercial potential. Commercially Reasonable Efforts shall be [**********].

1.30 "Committee" shall mean any of the JSC, JDC, JCC, JFC, JPSC, any CRCC, and any other committee established by the Parties or by the Committees referenced above under this Agreement, each as described in ARTICLE III (together with Working Groups and other committees contemplated herein or established in accordance with this Agreement).

1.31 "Common Stock" shall mean the common stock of Parent, par value $0.001 per share.

1.32 "Common Technical Document" shall mean the dossier intended to support the Regulatory Filing for Marketing Approval of the Product in the United States and, subject to Teva performing the applicable Ex-U.S. Development Activities, the European Union using the Common Technical Document format that was developed by the ICH.

1.33 "Company Core Data Sheet" shall mean the document that specifies the essential information concerning the Product that is required to be provided to Healthcare Prescribers regarding the use of the Product, including information relating to safety, indications, dosing and pharmacology, as such document is described in ICH guidance E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs, November 1996 (published by the FDA in the Federal Register in May 1997), as amended from time to time.

1.34 "Competing Product" shall mean [**********].

1.35 "Contract Sales Force" shall mean sales representatives employed by a Third Party.

1.36 "Control" or "Controlled" shall mean, with respect to any item of material, regulatory documentation, Product Trademark, Know-How (including Product Information or Party Information), Patents or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise, to assign, or grant a license, sublicense, right of reference or other right to or under such material, regulatory documentation, Product Trademark, Know-How, Patents or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.37 "Co-Promote," "Co-Promotion" or "Co-Promoting" shall mean the joint marketing and promotion of the Product by the Parties (or their respective Affiliates) under the same trademark in the United States pursuant to the U.S. Commercialization Plans.

1.38 "Country/Region Commercialization Budget" shall mean the budget for a particular Calendar Year prepared by Teva, with Regeneron's meaningful participation and input, and submitted to the JCC (through the applicable Country/Region Commercialization Committee) and approved by the JSC for the applicable Country/Region Commercialization Plan.

1.39 "Country/Region Commercialization Plan" shall mean, for each Reporting Country/Region in the Ex-U.S. Territory, the [**********] rolling plan for Commercializing the Product in the Field in such country or Region and the related Country/Region Commercialization Budget and a non-binding budget forecast for the next [**********], prepared by Teva, with Regeneron's meaningful participation and input, and submitted to the JCC (through the applicable Country/Region Commercialization Committee) and approved by the JSC, as each may be amended from time-to-time in accordance with the terms of this Agreement. Without limitation, each Country/Region Commercialization Plan shall set forth, for the Product in the applicable Reporting Country/Region, the information, plans and forecasts set forth in Section 6.2(c).

1.40 "Detail" shall mean a face-to-face, interactive selling presentation for the Product in the Field by a representative of a Party's sales force, to a Healthcare Prescriber in the Field in the Territory, but excluding, for clarity: (a) e-details; (b) presentations made at conventions or to any group of more than [**********] Healthcare Prescribers; or (c) a delivery of samples of the Product (either directly or through the use of a sample form), savings cards or coupons without discussion with a Healthcare Prescriber. For the avoidance of doubt, National Account Managers, reimbursement specialists and MSLs do not Detail the Product.

1.41 "Detailing Percentage" shall mean, with respect to Details of the Product in the United States by a sales representative, [**********].

1.42 "Develop," "Development" or "Developing" shall mean: (a) activities relating to research, pre-clinical and clinical drug development of the Product in the Field, including, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical trials (including research to design clinical trials and activities of MSLs to support such clinical trials prior to the First Commercial Sale in the U.S.), regulatory affairs, project management, drug safety surveillance activities (including establishing, holding and maintaining the global safety database prior to the First Commercial Sale in the U.S.) related to clinical trials, the preparation and submission of Registration Filings but excluding activities (other than clinical trials in support

of Pricing Approvals for the Ex-U.S. Territory, which, for clarity, shall be Ex-U.S. Development Activities, and clinical trials in support of Pricing Approvals for the United States, which for clarity, shall be included in the Global Development Plan) necessary to obtain and maintain Pricing Approvals, reimbursement or listing on health care providers' and payers' formularies, (b) the development of any device or delivery system that is developed for use with, or otherwise included in, the Finished Product, (c) the development of any companion diagnostics for use with the Product, and (d) any other research and development activities with respect to the Product in the Field, including, activities to support the discovery of biomarkers and activities to support new product formulations, delivery technologies or new Indications in the Field, either before or after the First Commercial Sale; [**********]. For clarity, the terms "Develop," "Development" and "Developing" are used herein with respect to the Product while the terms "develop," "development" and "developing" are used herein with corresponding meanings with respect to other products.

1.43 "Development Budget" shall mean the Global Development Budget or the Ex-U.S. Territory Development Budget, as the context requires.

1.44 "Development Costs" shall mean, [**********], costs and expenses incurred by a Party or its Affiliates for the Product, from and after the Effective Date directly in connection with the Development of the Product in the Field in accordance with this Agreement and the applicable Development Plan, including:

(a) all Out-of-Pocket Costs, including fees and expenses associated with preparing and submitting Registration Filings (other than for Pricing Approvals) and obtaining Marketing Approvals necessary for the Development and Commercialization of the Product in the Field under this Agreement in accordance with such Development Plan, but excluding amounts captured under Section 7.1(d) as Other Shared Expenses;

(b) Development FTE Costs;

(c) Development Supply Costs;

(d) Commercial Supply Costs for any Product Manufactured prior to the First Commercial Sale in the United States to meet the Commercial Supply Requirements for the United States;

(e) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation [**********], (ii) Manufacturing scale-up and improvements (including Manufacturing Process Improvements), (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), (v) the development of any device or delivery system for use with, or that otherwise is included in, the Finished Product, and (vi) internal and Third Party costs

and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) establishing a primary or secondary source supplier, which, for clarity, may be an Affiliate of Regeneron or a Third Party contract manufacturing organization, including, the transfer of process and Manufacturing technology and analytical methods (whether such transfer occurs before or after the First Commercial Sale), scale-up, process and equipment validation, cleaning validation, capital expenditures, and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Development Supply Costs or Commercial Supply Costs);

(f) any other costs or expenses specifically identified and included in such Development Plan or expressly included as Development Costs under this Agreement.

[**********].

1.45 "Development FTE Cost" shall mean, for all Development activities performed in accordance with a Development Plan, including regulatory activities, the product of (a) the number of FTEs required for such Development activities as set forth in such approved Development Plan and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs unless the JFC determines a separate FTE Rate for such personnel in lieu of such Out-of-Pocket Costs.

1.46 "Development FTE Rate" shall mean the applicable FTE Rate listed on Exhibit C for FTEs performing Development activities in accordance with a Development Plan, including regulatory activities with respect thereto, as such FTE Rate may be adjusted from time to time as set forth in the definition of "FTE Rate".

1.47 "Development Plan" shall mean the Global Development Plan or Ex-U.S. Territory Development Plan, as the context requires.

1.48 "Development Principal Party" shall mean, with respect to Development activities for the Product under this Agreement, the Party that has principal responsibility for such Development activities as set forth in Section 5.2.

1.49 "Development Supply Cost" shall mean, with respect to the Development of the Product under a Development Plan or an Additional Trial Plan, (a) the Out-of-Pocket Cost for purchasing or the Manufacturing Cost to Manufacture Finished Product for Development Supply Requirements for activities contemplated under such Development Plan or such Additional Trial Plan, as applicable, (b) the Out-of-Pocket Cost for purchasing or the Manufacturing Cost to Manufacture, comparator agent, combination agent, or placebo requirements for activities contemplated under the applicable Development Plan or such Additional Trial Plan, as applicable, (c) the Out-of-Pocket Cost or the Manufacturing Cost for filling, packaging, labeling, device

manufacture and assembly, and delivery of such Development Supply Requirements (or with respect to any Additional Trial, the Product), comparator agent, combination agent or placebo, as the case may be, for activities contemplated under such Development Plan or such Additional Trial Plan, as applicable and (d) any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of Development Supply Requirements.

1.50 "Development Supply Requirements" shall mean (a) the quantities of the Product that are required by a Party or the Parties for Development in the Field under this Agreement, including the conduct of research, pre-clinical studies and clinical trials, validation activities, stability testing, device development and other non-clinical demands in connection with a Development Plan or an Additional Trial Plan and (b) quantities of the Product that are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.

1.51 "Distributor/Commercial Partner" shall mean, with respect to a country in the Territory, a Third Party (including a Sublicensee) to whom a Party supplies the Product for marketing, sale or distribution by such Third Party in such country, irrespective of whether a license, sublicense or right of reference is granted to such Third Party or whether such Third Party holds the Approval for the Product in such country; *provided*, *however*, the term "Distributor/Commercial Partner" shall not include any such Third Party that is not a Sublicensee [**********].

1.52 "Dollars" or "$" shall mean United States Dollars.

1.53 "EMA" shall mean the European Medicines Agency or any successor agency thereto.

1.54 "European Union" shall mean the organization of member states of the European Union, as it may be constituted from time to time; *provided that* for the purposes of this Agreement the United Kingdom and any other country that is a member of the European Union on the Effective Date, shall be deemed to be a member of the European Union even if such country ceases to be a member of the European Union during the term of this Agreement.

1.55 "Excluded Territory" shall mean Japan, South Korea, Taiwan, Indonesia, Thailand, Philippines, Malaysia, Singapore, Vietnam, Myanmar and Sri Lanka.

1.56 "Executive Officers" shall mean, with respect to Regeneron, the Chief Executive Officer of Parent, and with respect to Teva, the Chief Executive Officer of the Controlling Parent for Teva, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.57 "Existing Agreements" means the [**********]. All Existing Agreements as of the Effective Date are set forth on Schedule 1.57.

1.58 "Ex-U.S. Territory" shall mean all countries in the Territory other than the United States.

1.59 "Ex-U.S. Territory Commercialization Budget" shall mean the budget(s) for a particular Calendar Year for Commercialization under the Ex-U.S. Territory Commercialization Plan [**********] developed by the JCC and submitted to and approved by the JSC.

1.60 "Ex-U.S. Territory Commercialization Plan" shall mean the [**********] rolling plan prepared by Teva, with Regeneron's meaningful participation and input, and submitted to the JCC and approved by the JSC for Commercializing the Product in the Ex-U.S. Territory, including the related Ex-U.S. Territory Commercialization Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Without limitation, each Ex-U.S. Territory Commercialization Plan shall set forth (if not otherwise set forth in the applicable Country/Region Commercialization Plan(s)) for the Product in the Ex-U.S. Territory, the information, plans and forecasts set forth in Section 6.2(b).

1.61 "Ex-U.S. Territory Development Budget" shall mean the budget(s) for the Ex-U.S. Territory Development Plan for a particular Calendar Year [**********] developed by the JDC and submitted to and approved by the JSC pursuant to Section 5.3(d).

1.62 "Ex-U.S. Territory Development Plan" shall mean the [**********] rolling plan for Development in the Ex-U.S. Territory that is required solely to support Approval of the Product in the Ex-U.S. Territory (and, for clarity, not outside the Ex-U.S. Territory) in, [**********] as the Product is being Developed under the Global Development Plan or any Regeneron Additional Trial Plan [**********] (all such Development ((a) and (b)), "Ex-U.S. Territory Development Activities"), including the related Ex-U.S. Territory Development Budget as each may be amended from time to time in accordance with the terms of this Agreement. [**********].

1.63 "Ex-U.S. Territory Global Commercialization Costs" shall mean [**********] of the Global Commercialization Costs.

1.64 "Ex-U.S. Territory License" shall mean any License to intellectual property rights [**********] the Product in the Field in the Ex-U.S. Territory under the Ex-U.S. Territory Development Plan or Ex-U.S. Territory Commercialization Plan, as applicable, that would not reasonably be expected to [**********].

1.65 "Ex-U.S. Territory Product Changes" shall mean changes to the dose, formulation, delivery, Manufacturing or other changes to the form or Manufacturing of the Product

for Commercialization in the Ex-U.S. Territory compared to the dose, formulation, delivery, form or Manufacturing of the Product for Commercialization in the United States requested by Teva or requested or required by a Regulatory Authority.

1.66 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.67 "Field" shall mean the prevention, delay, palliation, diagnosis or treatment of any disease, state or condition in humans.

1.68 "Field Force Cost" shall mean, with respect to the Commercialization of the Product in the United States, beginning on the First Commercial Sale in the United States the product of (a) the number of sales representatives, reimbursement representatives, NAMs and MSLs (collectively, "Field Force Personnel") (with the number and the method of calculating such number set forth in the U.S. Commercialization Plan), (b) the applicable Field Force FTE Rate and (c) with respect to a sales representative who Details the Product in the United States, a percentage for such sales representative using the applicable Detailing Percentage based on the number and position of Details of the Product performed by such sales representative in accordance with this Agreement and the U.S. Commercialization Plan, which percentage may be determined by the JCC for a particular sales force in the aggregate based on the Health Care Prescribers Detailed by such sales force and the overall number and position of Details of the Product performed by such sales force. For the avoidance of doubt, [**********].

1.69 "Field Force FTE Rate" shall mean the applicable FTE Rates listed on Exhibit C for each category of Field Force Personnel, as such FTE Rate may be adjusted from time to time as set forth in the definition of "FTE Rate".

1.70 "Finished Product" shall mean the Product in the Field in its finished, labeled, assembled, and packaged form, ready for sale to the market or use in clinical trials or pre-clinical studies, as the case may be.

1.71 "First Commercial Sale" shall mean, with respect to the Product in a country in the Territory, the first (1^{st}) commercial sale of the Finished Product to a Third Party that is not a Distributor/Commercial Partner for use or consumption in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

1.72 "Formulated Bulk Product" shall mean the Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.73 "FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party or its Affiliates and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [**********] hours per year. For clarity, unless otherwise expressly provided in this Agreement or a Plan, FTEs shall not include information technology, human resources, finance or legal personnel.

1.74 "FTE Costs and Expenses" shall mean the sum of (a) all costs and expenses for the employee providing the applicable services, including salaries, wages, bonuses, commissions, benefits, profit sharing, stock option grants, FICA costs and other similar ex-U.S. costs, travel, meals and entertainment, training, recruiting, relocation, operating supplies, and equipment and other disposable goods to the extent required for the performance of the applicable services, (b) a pro rata allocation of equipment maintenance costs, utilities, general, administrative and facilities expenses, including allocated building operating costs and depreciation and repairs and maintenance and (c) other overhead, including costs and expense for information technology, human resources, finance and legal, in any case ((a), (b) or (c)), whether internal costs and expenses or amounts paid to Third Parties.

1.75 "FTE Rate" shall mean the separate rates as set forth in Exhibit C for the U.S. or Ex-U.S. Territory (as may be further divided by country or region therein) and respective activity of the FTE as set forth therein, which represents the fully burdened rate for such FTE and includes all FTE Costs and Expenses for such FTE. Each FTE Rate shall be adjusted as of January 1, 2017 and annually thereafter by an amount equal to [**********]. For clarity, the JFC may determine (a) a separate FTE Rate for (i) contractors performing Development activities under this Agreement in lieu of charging the activities of such contractors as Out-of-Pocket Costs, or (ii) sales representatives that Detail different Healthcare Prescribers (e.g. primary care versus and among different specialist, such as rheumatology, orthopedic medicine, pain medicine or neurology) and (b) a separate indexed adjustment mechanism for adjusting any FTE Rate for personnel located outside the United States. For clarity, as specified in Section 3.11(c) and Section 10.4, to the extent any dispute with respect to FTE Rate becomes an Unresolved Matter, such dispute will be treated as a Financial Dispute.

1.76 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.

1.77 "Global Commercialization Costs" shall mean, [**********], the Out-of-Pocket Costs incurred by a Party or its Affiliates directly in connection with the performance of Global Commercialization Activities in accordance with this Agreement and the U.S. Commercialization Plan.

1.78 "Global Development Budget" shall mean the budget(s) for a particular Calendar Year [**********] submitted to and approved by the JSC pursuant to Section 5.3(d) for the applicable Global Development Plan.

1.79 "Global Development Cap" shall mean, with respect to the clinical trials (and supporting Development) for the Set Indications and any Selected Combination Therapy, an amount equal to [**********] plus [**********] of any Global Development Budget for any Development in support of Selected Global Indications or Selected Combination Therapies that are approved consensually [**********].

1.80 "Global Development Plan" shall mean the written [**********] rolling plan for Development of the Product to support Marketing Approval of the Product in the United States and by the EMA for the Set Indications and any Selected Combination Therapy, including any Manufacturing Process Improvements regardless of whether any such Manufacturing Process Improvements occur before or after Approval of the Product, including the related Global Development Budget, as each may be amended from time to time in accordance with the terms of this Agreement.

1.81 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMA or the ICH, or other country regulatory agencies, as applicable.

1.82 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.83 "Healthcare Prescriber" shall mean in any state, country or jurisdiction, any physician or other medical professional with prescribing authority (including a nurse practitioner or physician assistant with prescribing authority) for the Product in such state, country or jurisdiction.

1.84 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.85 "IFRS" shall mean International Financial Reporting Standards of the International Accounting Standards Board.

1.86 "IND" shall mean, with respect to the Product in the Field, an Investigational New Drug Application filed with the FDA pursuant to 21 C.F.R. § 312 before the commencement

of clinical trials involving the Product, including all amendments and supplements to such application or any equivalent filing with any Regulatory Authority outside the United States.

1.87 "Indication" shall mean any disease, state or condition.

1.88 "Initial Global Development Plan" shall mean the initial Global Development Plan, which is attached hereto as Schedule 1 and deemed approved by the JSC as of the Effective Date.

1.89 "Initial Indication" shall mean each of (a) osteoarthritic pain and (b) chronic lower back pain, individually. The Parties acknowledge that the medical description of osteoarthritic pain or chronic lower back pain in certain countries in the Territory may not be phrased in exactly the same words as in this Agreement, and Initial Indication shall include any condition that is phrased in medical terms of substantially similar meaning, or in medical terms encompassing a substantially similar meaning.

1.90 "Joint Patent Rights" shall mean Patents that cover or claim a Joint Invention.

1.91 "Know-How" shall mean, with respect to each Party and its Affiliates and its and their Distributors/Commercial Partners and subcontractors, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information, including marketing and supply information (whether or not patentable or otherwise protected by trade secret Law) and that are not claimed by such Party's or such Party's Affiliates' or its or their Distributors/Commercial Partners' or subcontractors' issued Patents.

1.92 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions or ordinances of any Governmental Authority.

1.93 "Lead Commercialization Party" shall mean, with respect to the United States, Regeneron, and with respect to any country in the Ex-U.S. Territory, Teva.

1.94 "Lead Regulatory Party" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings (or portion thereof) and any Approvals (or portion thereof) for the Product in the Field and for related regulatory duties, in each case, as set forth in Section 7.1.

1.95 "Legal Dispute" shall mean (a) any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement, excluding any dispute, controversy or claim with respect to any intellectual property (including Know-How, Patents and copyrights) that is subject to resolution pursuant to Article XI,

Article XII or Article XIII, and (b) any disputed matters specifically identified as a "Legal Dispute" hereunder.

1.96 "License" shall mean any license or other agreement to acquire rights from a Third Party, which license or other agreement is entered into during the Term and has been approved by the JSC pursuant to Sections 3.2, 3.11, 13.3(h) or 13.3(i) for the Development, Manufacture or Commercialization of the Product in the Field in the Territory under this Agreement [**********].

1.97 "Major Market Country" shall mean any of the following: [**********].

1.98 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, device manufacture and assembly, quality assurance testing and release, shipping and storage of Finished Product (including manufacturing Formulated Bulk Product and any device or delivery system with respect to the Finished Product), placebo or a comparator agent, as the case may be, or the development thereof, including test method development and stability testing, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up, cell-line development, data collection and management, project management, and regulatory affairs, including the preparation and submission of Registration Filings, with respect to the foregoing.

1.99 "Manufacturing Development Activities" shall mean all Development activities regarding the Manufacture of the Product for the Territory, [**********].

1.100 "Manufacturing Information" shall mean [**********].

1.101 "Manufacturing Process Improvements" shall have the meaning set forth in Section 8.7.

1.102 "Marketing Approval" shall mean an Approval required for the marketing and sale of the Product in the Field in a country in the Territory, but excluding any IND or separate Pricing Approval.

1.103 "Marketing Guidelines" shall mean the U.S. Marketing Guidelines, the Ex-U.S. Territory Marketing Guidelines, and, to the extent not inconsistent with the foregoing, the Territory Marketing Guidelines.

1.104 "Mid-Market Country" shall mean any of the following: [**********].

1.105 "Mitsubishi Agreement" shall mean the Collaboration Agreement, dated as of September 29, 2015, by and between Regeneron and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi"), as such agreement may be amended from time to time; [**********].

1.106 "MSLs" shall mean a medical science liaison employed by Party or any of its Affiliates to perform activities with respect to the Product.

1.107 "NAM" means a national account manager responsible for seeking coverage, coding and reimbursement of the Product by payers and managed market plans.

1.108 "Net Sales" shall mean, with respect to the Product for any period, the gross amount billed or invoiced by a Party, its Affiliates or its or their Distributor/Commercial Partners for the sale of the Product to Third Parties (the "Invoiced Sales"), less deductions for the following (all calculated in accordance with the Accounting Standards):

(a) normal and customary trade, cash, quantity and prompt settlement discounts (including chargebacks and free goods allowances) actually allowed;

(b) amounts repaid or credited by reason of rejection, return or recall of goods, rebates or *bona fide* price reductions (retroactive or otherwise);

(c) freight, postage, shipping, insurance and other transportation expenses to the extent that such items are included in the Invoiced Sales;

(d) fees for services provided by distributors/wholesalers (other than Distributors/Commercial Partners) related to the distribution of the Product;

(e) customs and excise duties and other taxes or duties related to the sales (but specifically excluding income tax) to the extent that such items are included in the Invoiced Sales;

(f) rebates, chargebacks and other amounts paid with respect to sales paid for by any Governmental Authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental programs;

(g) the portion of administrative fees paid or discounts provided during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to the Product;

(h) compulsory refunds, credits, rebates and other similar payments directly related to the sale of the Product, accrued, paid or deducted pursuant to an agreement with any Third Party payor (other than a Governmental Authority);

(i) co-pay assistance directly related to the sale of the Product, accrued, paid or deducted pursuant to an agreement; and

(j) any other similar and customary deductions that are consistent with the applicable Accounting Standards.

Net Sales in currency other than Dollars shall be converted into Dollars according to the provisions of Section 9.13. Any of the deductions listed above that involves a payment by a Party or its Affiliates or its or their Distributor/Commercial Partners shall be taken as a deduction in the Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, the Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions of the Product for pre-clinical or clinical purposes or as samples, in each case, without charge. A Party's or its Affiliates' or its or their Distributor/Commercial Partners' transfer of the Product to an Affiliate or Distributor/Commercial Partner shall not result in any Net Sales, unless such Affiliate or Distributor/Commercial Partner, as applicable, is the end user of, or otherwise consumes, the Product in the course of its commercial activities. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but that are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of the Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties.

1.109 "NGF" shall mean the neuropeptide known as "Nerve Growth Factor" or "NGF".

1.110 "Non-Approval Trials" shall mean any post-marketing surveys, registries and clinical trials post-first Marketing Approval not intended to gain additional labeled Indications, but excluding any post-first Marketing Approval clinical trials required by Regulatory Authorities to maintain Marketing Approvals of existing labeled Set Indication(s) or Selected Combination Therapies. For clarity, clinical trials in support of Pricing Approval are not Non-Approval Trials.

1.111 "Non-Conducting Party" shall mean, with respect to an Additional Trial, the Party that is not the Conducting Party with respect to such Additional Trial.

1.112 "Non-Field Force Commercial FTE Cost" shall mean, the product of (a) the number of Non-Field Force Commercial FTEs and (b) the Non-Field Force Commercial FTE Rate. For the avoidance of doubt, "Non-Field Force Commercial FTE Costs" shall not include any costs and expenses related to (x) personnel to the extent performing any activities, or who have responsibilities, with respect to the Commercialization of the Product outside of the United States, or (y) activities or personnel covered by or otherwise included in Field Force Costs, [**********], Other Shared Expenses or Shared Commercial Expenses (other than the Non-Field Force Commercial FTE Cost component thereof).

1.113 "Non-Field Force Commercial FTE Rate" shall mean, the applicable FTE Rate listed on Exhibit C for Non-Field Force Commercial FTEs, as such FTE Rate may be adjusted from time to time as set forth in the definition of "FTE Rate".

1.114 "Non-Field Force Commercial FTEs" shall mean those FTEs conducting product management and marketing, market research, contract administration, fleet administration, sales operations (e.g., physician targeting, incentive compensation administration and sales training), sample fulfillment and accountability, sales material fulfillment, advertising operations, convention planning, medical information, medical compliance, medical education activities, maintenance of Approvals, management of Non-Approval Trials, business analytics, market access, commercial pharmacovigilance, scientific publications, health economic and outcome research, pricing activities (including obtaining and maintaining Pricing Approvals, reimbursement or listing on health care providers' and payers' formularies), procurement services, customer service, trade administration and other Commercialization activities not performed by Field Force Personnel, in each case, to the extent attributable to the Commercialization of the Product in the Field in the United States under and in accordance with the approved U.S. Commercialization Plan and performed after the First Commercial Sale in the United States.

1.115 "Other Component" shall mean (a) an active ingredient other than the anti-NGF antibody known as of the Effective Date as fasinumab or REGN475, or (b) any product (other than the Product) containing or incorporating such active ingredient contemplated by clause (a).

1.116 "Other Indication" shall mean any (a) Initial Indication, (b) Selected Global Indication, or (c) [**********], in each case ((a), (b), and (c)), that is not osteoarthritic pain.

1.117 "Other Shared Expenses" shall mean, [**********], those costs and expenses specifically referred to in Sections [**********].

1.118 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the paying Party's Accounting Standards) by either Party or its Affiliates in connection with activities under this Agreement, excluding FTE Costs and Expenses.

1.119 "Parent" shall mean Regeneron Pharmaceuticals, Inc., a New York corporation and the ultimate parent company of Regeneron, or any successor thereto.

1.120 "Party Information" shall mean, with respect to a Party, all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information (whether or not patentable or protectable as a trade secret) not generally known to the public (in each case, other than Product Information and Joint Inventions), including information of a Third Party for which the disclosing Party has a duty to maintain such

information as confidential, that are disclosed or made available under this Agreement by or on behalf of a Party or such Party's Affiliates to the other Party or the other Party's Affiliates or its or their subcontractors, distributors (including Distributor/Commercial Partners) or other Persons working on its or their behalf under this Agreement. For clarity, Party Information does not include Product Information or Joint Inventions.

1.121 "Patent Cooperation Treaty" or "PCT" shall mean the Patent Cooperation Treaty, opened for signature June 19, 1970, 28 U.S.T. 7645.

1.122 "Patents" shall mean (a) all national, regional and international patents and patent applications, including, provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including, divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including, utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including, revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including, so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.123 "Person" shall mean and include an individual, a partnership, a joint a venture, a limited liability company, a corporation, a firm, a trust, an unincorporated organization and a government or other department or agency thereof.

1.124 "Phase III Clinical Trial" means a registration or pivotal clinical trial performed in subjects with a particular disease or condition that is designed in a randomized, controlled fashion to establish the dose, efficacy and safety of a product given its intended use and to define warnings, precautions and adverse events that are associated with such product in the dosage range intended to be prescribed. This clinical trial may be conducted in lieu of conducting a separate "phase 2 clinical trial" that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(b) (or its equivalent under the applicable Laws of any country in the Ex-U.S. Territory) and "phase 3 clinical trial" that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(c) (or its equivalent under the applicable Laws of any country in the Ex-U.S. Territory) and may be bridged to larger studies. For clarity, a substudy of an existing Phase III Clinical Trial that is used as a pivotal study for a particular disease or condition shall constitute a Phase III Clinical Trial.

1.125 "PHSA" shall mean the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.126 "Plan" shall mean the U.S. Commercialization Plan, Ex-U.S. Territory Commercialization Plan, Global Development Plan, Ex-U.S. Territory Development Plan, any Country/Region Commercialization Plan, or other plan approved through the Committee process relating to the Development or Commercialization of the Product in the Field under this Agreement other than an Additional Trial Plan.

1.127 "Platform License" shall mean any License for any technology platform, manufacturing or formulation technology, delivery device or other similar technology that is generally applicable to the Product and to other products.

1.128 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for the Product that can be charged to consumers or that will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.129 "Product" shall mean the product (in any dosage, form, formulation, presentation or package configuration) that contains as its sole active ingredient the anti-NGF antibody known as of the Effective Date as fasinumab or REGN475. For clarity, "Product" shall include [**********].

1.130 "Product Information" shall mean any and all ideas, inventions, information, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public that arise or are conceived or developed under or in connection with this Agreement by (a) either Party or its Affiliates or its or their Distributors/Commercial Partners or subcontractors or (b) the Parties or their Affiliates or its or their Distributors/Commercial Partners or subcontractors jointly, in each case ((a) and (b)) to the extent [**********].

1.131 "Product Trademark" shall mean, with respect to the Product in the Field in the Territory, the trademark(s) selected by the JCC for use on the Product in one or more countries in the Territory and accompanying logos, slogans, trade names, trade dress or other indicia of origin, in each case as selected by the JCC in accordance with Section 11.2.

1.132 "Promotional Materials" shall mean all promotional, advertising, communication and educational materials relating to the Product for use in connection with the

marketing, promotion and sale of the Product in the Field in the Territory, and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.133 "Quality Agreement" shall mean the Clinical Quality Agreement or the Commercial Quality Agreement, as applicable.

1.134 "Quarter" or "Quarterly" shall mean each respective period of three (3) consecutive calendar months commencing on January 1, April 1, July 1 and October 1 during the Term, except that the first (1st) Quarter shall commence on the Effective Date and shall end on September 30, 2016 and the last Quarter shall end on the last day of the Term.

1.135 "Regeneron Additional Trial" shall mean an Additional Trial for which Regeneron is the Conducting Party.

1.136 "Regeneron Additional Trial Plan" shall mean the Additional Trial Plan for a Regeneron Additional Trial.

1.137 "Regeneron Background Patent Rights" shall mean the Regeneron Patent Rights that are not Regeneron Product Patent Rights.

1.138 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and the Regeneron Know-How.

1.139 "Regeneron Know-How" shall mean all Know-How that is Controlled as of the Effective Date and at any time during the Term by Regeneron or any of its Affiliates (other than the Joint Inventions and other than by operation of the license and other grants in ARTICLE XII) and relates to the Product and is necessary or reasonably useful for the Development or Commercialization of the Product in the Field, excluding any Joint Inventions and any Know-How that is claimed by the issued Regeneron Background Patent Rights, Regeneron Manufacturing Patents or Regeneron Product Patent Rights. For clarity, Regeneron Know-How shall include Product Information, [**********].

1.140 "Regeneron Manufacturing Patents" shall mean those Patents Controlled as of the Effective Date or hereafter during the Term by Regeneron or any of its Affiliates that include at least one (1) Valid Claim that, absent a license from Regeneron or any of its Affiliates, would be infringed (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue) by either the Manufacture of the Product (or any component or intermediate thereof) or the Development or Commercialization of the Product (or any component or intermediate thereof) so Manufactured; *provided that* [**********].

1.141 "Regeneron Patent Rights" shall mean those Patents Controlled as of the Effective Date or hereafter during the Term by Regeneron or any of its Affiliates (other than by operation of the license in ARTICLE XII and other than the Joint Patent Rights and the Regeneron Manufacturing Patents) that include at least one (1) Valid Claim that, absent a license from Regeneron or any of its Affiliates, would be infringed (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue) by the use, sale or offer for sale (including Commercialization), or import of the Product in the Field in the Territory by Teva, including any Patent that claims any Product Information or Product Invention but excluding any Regeneron Manufacturing Patents.

1.142 "Regeneron Product Patent Rights" shall mean Regeneron Patent Rights that claim the composition of matter of, or a pharmaceutical preparation that includes as its sole active ingredient, any Competing Product (including the Product), or any method of use of any Competing Product (including the Product), including any Regeneron Patent Right that claims any Product Information or Product Invention. Schedule 1.142 lists all of the Regeneron Product Patent Rights in existence as of the Effective Date.

1.143 "Regeneron Target Healthcare Prescribers" shall mean Healthcare Prescribers primarily practicing in [**********].

1.144 "Region" shall mean (a) the United States, and (b) such countries or group of countries in the Ex-U.S. Territory as determined by the JCC.

1.145 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, any testing, marketing authorization application, supplementary application or variation thereof, IND, BLA, or any equivalent applications in any country.

1.146 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of the Product in the Field under this Agreement. The term "Regulatory Authority" includes the FDA and the EMA.

1.147 "Reporting Country/Region" shall mean (a) each Major Market Country, and (b) each other country or Region as determined by the JCC pursuant to Section 3.5.

1.148 [**********].

1.149 [**********].

1.150 "Selected Combination Therapy" shall mean a Proposed Combination Therapy that is the subject of a Development Proposal selected by the JSC pursuant to Section 5.4(a) for Development under the Global Development Plan or an [**********] for which the Product receives Marketing Approval in the United States or has otherwise been added under the Global Development Plan in accordance with this Agreement.

1.151 "Selected Global Indication" shall mean a Proposed New Indication that is the subject of a Development Proposal selected by the JSC pursuant to Section 5.4(a) for Development under the Global Development Plan or an [**********] for which the Product receives Marketing Approval in the United States or has otherwise been added under the Global Development Plan in accordance with this Agreement.

1.152 "Sensitive Information" shall mean [**********].

1.153 "Set Indication" shall mean an Initial Indication or Selected Global Indication.

1.154 "Shared Commercial Expenses" shall mean the sum of the following items incurred by a Party or its Affiliates, in each case to the extent directly attributable to Commercialization of the Product in the Field in the United States:

(a) Regeneron shall be permitted to take an allowance of [**********] of Net Sales in the Field in the United States to cover the cost of distribution, freight, insurance and warehousing, related to the sale of the Product in the Field in the United States, to the extent such costs are not included in the Manufacturing Costs, Development Supply Costs or Commercial Supply Costs, less any amount deducted from Net Sales pursuant to clause (c) or (d) of the definition of Net Sales;

(b) bad debt incurred by Regeneron and its Affiliates attributable to the Product in the Field sold in the United States;

(c) Field Force Cost in accordance with the approved U.S. Commercialization Plan;

(d) Out-of-Pocket Costs related to (i) the marketing, advertising or promotion of the Product in the Field in the United States (including pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia, Promotional Materials, patient support programs (including charitable contributions), direct to consumer campaigns and, except as otherwise set forth in Section 6.7, contract personnel, including any Contract Sales Force), (ii) market research for the Product in the Field in the United States or (iii) the preparation of training and communication materials for the Product in the Field in the

United States, in each case ((i), (ii) and (iii)), in accordance with the approved U.S. Commercialization Plan;

(e) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of the Product in the Field in the United States (including educational expenses, advocate development programs and symposia, and Promotional Materials) to the extent such marketing, advertising and promotion relate to both the Product and other products developed or commercialized by a Party or its Affiliates in accordance with the approved U.S. Commercialization Plan;

(f) Out-of-Pocket Costs related to Non-Approval Trials, medical affairs activities, or health economic outcomes research for the Product in the Field in the United States, including, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, in accordance with the approved U.S. Commercialization Plan and to the extent not included in Commercial Supply Cost;

(g) Out-of-Pocket Costs related to the maintenance of all Approvals directly related to the Commercialization of the Product in the Field in the United States;

(h) Non-Field Force Commercial FTE Costs in accordance with the approved U.S. Commercialization Plan;

(i) [**********] of the Global Commercialization Costs;

(j) Out-of-Pocket Costs for purchasing, or the Manufacture Cost for, Product samples or Product used in any bridging program;

(k) Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Registration Filing for Set Indications (or Selected Combination Therapies) and line extensions for the Product in the United States;

(l) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) that Regeneron or its Affiliate, as applicable, allocates to sales of the Product in accordance with Regeneron's or its Affiliate's standard policies and procedures consistently applied across its products, as applicable; and

(m) any other costs or expenses directly related to the Commercialization of the Product in accordance with the approved U.S. Commercialization Plan and not included in clauses (a) through (l) above other than the Ex-U.S. Territory Global Commercialization Costs;

in the case of [**********] solely to the extent incurred after First Commercial Sale in the United States. For clarity, the items set forth in the case of [**********] may be incurred at any time during the Term.

The foregoing shall not include any costs that have been included in Development Costs, [**********], Global Development Costs, Ex-U.S. Territory Development Costs, Other Shared Expenses or Ex-U.S. Territory Global Commercialization Costs. [**********].

1.155 "Shares of Then Outstanding Capital Stock" shall mean, at any time, the issued and outstanding shares of Common Stock and Class A Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, reclassification or similar transaction relating to Common Stock or Class A Stock distributable, on a pro rata basis, to all holders of Common Stock and Class A Stock.

1.156 "Target Healthcare Prescribers" shall mean, in the case of Regeneron, the Regeneron Target Healthcare Prescribers, and in the case of Teva, the Teva Target Healthcare Prescribers.

1.157 "Territory" shall mean all the countries and territories of the world other than the Excluded Territory.

1.158 "Teva Additional Trial" shall mean an Additional Trial for which Teva is the Conducting Party.

1.159 "Teva Additional Trial Plan" shall mean the Additional Trial Plan for a Teva Additional Trial.

1.160 "Teva Background Know-How" shall mean all Know-How that is Controlled as of the Effective Date and at any time during the Term by Teva or its Affiliates (other than the Teva Sole Inventions and Joint Inventions) and relates to the Product and is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Product in the Field, excluding Know-How that is claimed by issued Teva Sole Patent Rights, Teva Background Patent Rights or Joint Patent Rights.

1.161 "Teva Background Patent Rights" shall mean (a) those Patents Controlled as of the Effective Date or hereafter during the Term by Teva or any of its Affiliates (other than the Teva Sole Patent Rights or Joint Patent Rights) that include at least one (1) Valid Claim that, absent a license from Teva or any of its Affiliates, would be infringed (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue) by the development (including Development), manufacture (including Manufacture), use, sale or offer for sale (including Commercialization), or import of the Product in the Field by Regeneron and (b) any

Teva Sole Patent Right converted to a Teva Background Patent Right by Regeneron pursuant to Section 12.1(i).

1.162 "Teva Target Healthcare Prescribers" shall mean Healthcare Prescribers primarily practicing in [**********].

1.163 "Third Party" shall mean any Person other than Teva or Regeneron or any Affiliate of either Party.

1.164 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.

1.165 "U.S. Commercialization Budget" shall mean the budget(s) for a particular Calendar Year [**********] developed by the JCC and submitted to and approved by the JSC.

1.166 "U.S. Commercialization Plan" shall mean the [**********] rolling plan developed by the JCC and submitted to and approved by the JSC for Commercializing the Product in the U.S., including the related U.S. Commercialization Budget, as each may be amended from time-to-time in accordance with the terms of this Agreement. Without limitation, the U.S. Commercialization Plan shall set forth for the Product, the information, plans and forecasts set forth in Section 6.2(a).

1.167 "U.S. CPI" shall mean the Consumer Price Index – All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).

1.168 "Valid Claim" shall mean (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) that has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and that has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a Patent application.

1.169 "VAT" shall mean VAT, sales taxes, consumption taxes and other similar taxes required by applicable Law to be disclosed on the invoice.

1.170 Additional Definitions. Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE
ACP Proposal	2.6(b)(i)
Acquired Competing Product Election Period	2.6(b)(ii)
Acquired Competing Product Negotiation Period	2.6(b)(iii)
Acquired Competing Product Notice	2.6(b)(ii)
Acquiring Party	2.6(b)(i)
Additional CSF Member	6.7
Additional Trial	5.4(a)
[**********]	[**********]
Agreement	Preamble
Alliance Manager	3.12
Annual Inventory Report	9.9(d)
Anti-Corruption Laws	15.8(a)
AT Combination Therapy	5.4(a)
AT Indication	5.4(a)
Biosimilar Infringement	13.1(a)
Board .	20.15(a)(ii)
Budget Cap Overage	3.11(b)(ii)(B)
[**********]	[**********]
[**********]	[**********]
Co-Promote Commitment Level	6.4(b)
Co-Promote FTE Shortfall	6.7
Collaboration	Preamble
Collaboration Purpose	3.1(b)
Commercial Quality Agreement	8.6
Commercial Supply Agreement	8.5
Commercialization Overruns	9.8(b)
Conducting Party	5.4(a)
Controlling Parent	Definition of “Change of Control”
CRCC	3.5
Damages	17.1(a)
Default Interest Rate	9.14
Development Milestone Event	9.3(a)
Development Milestone Payment	9.3(a)
Development Overruns	9.8(a)
Development Proposal	5.4(a)
Development Quality Agreement	8.6
Development Supply Agreement	8.3
[**********]	[**********]
Effective Date	Preamble
Enforcing Party	13.1(d)
[**********]	[**********]

DEFINITION	SECTION/SCHEDULE
Expert	19.2(b)
Expert Determination	19.2(b)
[**********]	[**********]
Ex-U.S. Territory Development Activities	Definition of “Ex-U.S. Territory Development Plan”
Ex-U.S. Territory Development Costs	9.2(b)
[**********]	[**********]
[**********]	[**********]
Ex-U.S. Territory Marketing Guidelines	3.4(b)(ix)
Field Force Personnel	Definition of “Field Force Cost”
Financial Dispute	3.11(c)
First Party	13.1(b)
First Submission	19.2(b)
Force Majeure	ARTICLE XVIII
Fully Burdened Manufacturing Cost	Schedule 2
Global Commercialization Activities	6.2(a)(xiv)
Global Development Costs	9.2(a)
Global Development Cost True-Up	Schedule 3
Governance Disputes	10.2
Granting Party	12.4(c)
[**********]	[**********]
Indemnified Party	17.2
Indemnifying Party	17.2
Infringement	13.1(a)
Initial Purchase Price	9.6(a)
Investor	20.15(a)
Invoiced Sales	Definition of “Net Sales”
JSC	3.1(a)
JCC	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JPSC	3.1(a)
Joint Inventions	12.1(b)
knowledge	15.1
[**********]	[**********]
[**********]	[**********]
Manufacturing Cost	Schedule 2
Manufacturing Process Improvements	8.7
Mice	2.6(a)(i)
Mitsubishi	Definition of “Mitsubishi Agreement”
Modified Clause	20.6(a)

DEFINITION	SECTION/SCHEDULE
[**********]	[**********]
Non-Acquiring Party	2.6(b)(i)
Non-Enforcing Party	13.1(d)
Non-Scheduled Other Indication	9.3(b)(ii)
Offeror	20.15(a)(iii)
Officials	15.8(b)
Other Shared Expenses True-Up	Schedule 3
Party(ies)	Preamble
Parent CEO	13.3(b)(2)
[**********]	[**********]
Payment	15.8(b)
Permitted Commercialization Overrun	9.8(b)
Permitted Development Overrun	9.8(a)
[**********]	[**********]
Pricing Guidelines	3.2(b)(x)
Product Inventions	12.1(d)
Product Patent Rights	12.1(d)
Proposed Combination Therapy	5.4(a)
Proposed New Indication	5.4(a)
Purchase Price	9.6
Purchase Price Adjustments	9.6(c)
Purchase Price Adjustment A	9.6(b)
Purchase Price Adjustment B	9.6(c)
[**********]	[**********]
Quarterly Inventory Report	9.9(d)
Quarterly True-Up	Schedule 3
Quarterly True-Up Report	9.9(h)
Redacted Agreement	16.4
Referring Party	19.2(b)
Regeneron	Preamble
Regeneron Indemnitees	17.1(a)
Regeneron Sole Inventions	12.1(a)
Registration Meetings	7.1(a)
Representatives	15.8(b)
Responding Party	19.2(b)
Response	19.2(b)
Safety Data Exchange Agreement	7.4
[**********]	[**********]
Shared Commercial Expenses True-Up	Schedule 3
Shared Facility	Schedule 2
Shortfall Party	6.7
Sole Inventions	12.1(a)

DEFINITION	SECTION/SCHEDULE
Standstill Term	20.15(a)
Sublicensee	12.4(c)
Sublicense Agreement	12.4(c)
[**********]	[**********]
[**********]	[**********]
Term	19.1(a)
Termination Dispute	19.2(b)
Termination Notice Period	19.5
Territory Marketing Guidelines	3.4(b)(x)
Teva	Preamble
Teva Indemnitees	17.1(b)
[**********]	[**********]
Teva Sole Inventions	12.1(a)
Teva Sole Patent Rights	12.1(a)
Third Party Acquisition	2.6(b)(i)
Third Party Claim	17.1(a)
Third Party Infringement Claim	13.3(a)
Third Party Patent	13.3(c)(i)
[**********]	[**********]
True-Up	Schedule 3
Unresolved Matter	3.11(b)
USDTA	16.1(a)
U.S. Gross Profit	Schedule 3
U.S. Gross Profit Split	Schedule 3
[**********]	[**********]
U.S. Marketing Guidelines	3.4(b)(viii)
Working Group	3.1(a)

ARTICLE II
COLLABORATION

2.1 Scope of Collaboration. Upon and subject to terms and conditions of this Agreement, the Parties will cooperate in good faith to Develop and Commercialize the Product in the Field in the Territory in such a manner so as to optimize the commercial potential of the Product. The Parties shall establish various Committees as set forth in ARTICLE III of this Agreement to oversee and coordinate the Development and Commercialization of the Product in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in ARTICLE XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Product Information and such other information and materials as reasonably requested by the other Party

or as may be reasonably required for the Parties to operate effectively and efficiently under and in accordance with the terms and conditions of this Agreement; [**********].

2.2 Compliance With Law. Both Teva and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or that it believes, in good faith, may violate, any applicable Law.

2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish all information in its possession and control (or in its control and accessible by it consistent with its regular business practices) required for any filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement; [**********].

2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Licenses to which it is a party and to notify the other Party of any terms or conditions in any such License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement, including any sublicense under a License referenced in subsection (a) above, to which it is a party and that is related to the Collaboration, including any obligations to pay royalties, fees or other amounts due thereunder. Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, neither Party may terminate or amend any License or any other material agreement entered into pursuant to a Plan or an Additional Trial Plan if such termination or amendment would impose any material liability or restriction on either Party with respect to the Development or Commercialization of the Product in the Field in the Territory. With respect to each License entered into by a Party or its Affiliate hereunder [**********].

2.5 Commercially Reasonable Efforts; Plans. Subject to the terms of this Agreement, each Party (and its Affiliates) shall use Commercially Reasonable Efforts to fulfill all responsibilities assigned to it under this Agreement and any then-applicable Plans. The Parties shall

undertake all Development and Commercialization activities under this Agreement solely in accordance with the approved Plans, which may be amended from time to time as circumstances may require, each in accordance with this Agreement.

2.6 Limitation on Exercise of Rights Outside of Collaboration.

(a) Non-Compete. Except as otherwise set forth in this Agreement:

(i) During the Term, subject to Section 2.6(b) or Section 2.6(c), as applicable, neither Regeneron nor any of its Affiliates or its or their Distributor/Commercial Partners, either alone, or with or through any Third Party (including by way of any assignment, license, covenant or other transaction regarding intellectual property rights, or by any manufacture or supply of any materials), shall [**********]. For the avoidance of doubt, [**********], the foregoing restriction shall not limit Regeneron's rights outside of the Territory, including its rights to Develop and Manufacture the Product inside the Territory for commercialization or other exploitation outside the Territory. [**********].

(ii) Subject to Section 2.6(b), during the Term and, unless this Agreement is terminated by Teva pursuant to Section 19.2 or Section 19.3, continuing thereafter for a period of [**********], neither Teva nor any of its Affiliates or its or their Distributor/Commercial Partners, either alone, or with or through any Third Party (including by way of any assignment, license, covenant or other transaction regarding intellectual property rights, or by any manufacture or supply of any materials), shall [**********].

(b) Third Party Acquisitions.

(i) Notwithstanding Section 2.6(a), if as the result of an acquisition (including a Change of Control), (A) by a Third Party of, or (B) of a Third Party or a business or division of a Third Party by (each such acquisition ((A) or (B)), a "Third Party Acquisition"), a Party or one or more of its Affiliates (the "Acquiring Party"), the Acquiring Party acquires rights to a product that is an Acquired Competing Product, the Acquiring Party shall at its option (but is not required to), within [**********] after the closing of such Third Party Acquisition, present a proposal (an "ACP Proposal") to the other Party (the "Non-Acquiring Party") to include such Acquired Competing Product in the Collaboration based on the terms of this Agreement. As part of any such ACP Proposal, the Acquiring Party shall provide the Non-Acquiring Party with all information with respect to such Acquired Competing Product reasonably available to the Acquiring Party and material to a decision by the Non-Acquiring Party as to whether to approve the

inclusion of such Acquired Competing Product in the Collaboration, and to the extent in the Acquiring Party's possession and control (or in the Acquiring Party's control and accessible by the Acquiring Party consistent with the Acquiring Party's regular business practices), any such information reasonably requested by the Non-Acquiring Party.

(ii) The Non-Acquiring Party may, on or before the date that is [**********] after the receipt of such ACP Proposal (such [**********] period, the "Acquired Competing Product Election Period"), notify the Acquiring Party in writing (such notice, the "Acquired Competing Product Notice") that the Non-Acquiring Party elects to negotiate in good faith with the Acquiring Party the terms and conditions pursuant to which such Acquired Competing Product would be included in the Collaboration, including, any intellectual property thereto.

(iii) If the Non-Acquiring Party delivers an Acquired Competing Product Notice prior to the end of the Acquired Competing Product Election Period, then the Parties shall, for a period of [**********] or such longer period as the Parties may agree after the Non-Acquiring Party delivers the Acquired Competing Product Notice (such period, the "Acquired Competing Product Negotiation Period"), negotiate in good faith the terms and conditions pursuant to which such Acquired Competing Product would be included in the Collaboration. If the Parties agree on such terms and conditions prior to the end of the Acquired Competing Product Negotiation Period, then upon such agreement, the Acquired Competing Product shall be included in the Collaboration pursuant to such agreed terms and conditions.

(iv) If (A) the Acquiring Party does not deliver an ACP Proposal to the Non-Acquiring Party within [**********] after the closing of the applicable Third Party Acquisition, (B) the Non-Acquiring Party does not deliver an Acquired Competing Product Notice prior to the end of the Acquired Competing Product Election Period or (C) if the Non-Acquiring Party delivers an Acquired Competing Product Notice prior to the end of the Acquired Competing Product Election Period but the Parties are unable to reach agreement on the applicable terms and conditions prior to the end of the Acquired Competing Product Negotiation Period, then the Acquiring Party shall either [**********].

(v) The Acquiring Party shall conduct any research, development or commercialization of any Acquired Competing Product permitted under this Section 2.6(b) subject to appropriate firewall procedures to segregate such activities (and the personnel conducting such activities) from the activities performed by or

on behalf of the Acquiring Party pursuant to this Agreement to ensure that no Product Information, Party Information of the Non-Acquiring Party and no other information generated under or in connection with this Agreement is used in connection with such Acquired Competing Product activities.

(c) [**********].

2.7 Combination Products. The Parties acknowledge and agree that if the Parties desire to include a Combination Product in the Collaboration, then the Parties shall use good faith efforts to negotiate appropriate amendments to this Agreement to include such Combination Product as a Product hereunder, and if the Parties are unable to agree to such amendments, then such Combination Product shall not be included in this Agreement, and for clarity, shall be subject to Section 2.6.

2.8 Other Negative Covenants. During the Term and, unless this Agreement is terminated by Teva pursuant to Section 19.2 or Section 19.3, continuing thereafter for a period of [**********], neither Teva nor any of its Affiliates or its or their Distributor/Commercial Partners, either alone, or with or through any Third Party (including by way of any assignment, license, covenant or other transaction regarding intellectual property rights, or by any manufacture or supply of any materials), shall, anywhere in the world, [**********], without Regeneron's prior written consent.

ARTICLE III
INFORMATION EXCHANGE AND UPDATES; MANAGEMENT

3.1 Committees and Management.

(a) The Parties agree to establish, as provided and for the purposes specified herein, each of the following committees: a Joint Steering Committee (the "JSC"), a Joint Development Committee ("JDC"), a Joint Commercialization Committee (the "JCC"), CRCCs to the extent provided in Section 3.5, a Joint Finance Committee (the "JFC"), a Joint Product Supply Committee (the "JPSC"), and such other sub-committees as the JSC shall deem to be appropriate. The JSC, JDC, JFC, JPSC and the JCC shall be established within [**********] after the Effective Date and the JCC shall establish the CRCCs as provided in Section 3.5. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted

and shall operate as the Committee that establishes the Working Group determines. Subject to the terms of this ARTICLE III, (i) any one or more Committees established pursuant to this Agreement may have the same members appointed by each Party, and such members may meet to simultaneously discuss matters within the jurisdiction of such Committees, and (ii) a Party may appoint a member of one Committee to one or more other Committees notwithstanding whether the other Party appoints the same members to any such Committees.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential the Product in the Field in the Territory consistent with Commercially Reasonable Efforts (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Joint Steering Committee.

(a) Formation, Composition and Membership. The JSC shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated Development program for the Product in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.11 on which such Committees are unable to reach consensus. The JSC shall be composed of three (3) senior representatives of each Party; *provided that* the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually review and approve the Development Plans and Commercialization Plans; (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans; (iii) reconcile any inconsistencies between or among any of the U.S. Commercialization Plan, the Ex-U.S. Territory Commercialization Plan, and the Country/Region Commercialization Plan(s) for the Product; (iv) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy, Plan and budget issues; (v) review and discuss the results and data from any Additional Trial; (vi) approve Licenses or other agreements to acquire rights from a Third Party that are necessary or reasonably useful for the Development, Manufacture or Commercialization of the Product in the Field under this Agreement; (vii) subject to Section 3.1

(b), review and discuss the roles and responsibilities of the Committees and Working Groups and any proposals of the Parties or any such Committees or Working Groups related thereto, and establish Committees, Working Groups and sub-committees of the JSC, as the JSC deems appropriate; (viii) approve the Anticipated First Commercial Sale in the U.S.; (ix) review and approve any Ex-U.S. Territory Product Changes; (x) discuss and approve the general pricing strategy (including discounts, rebates and other price reductions) for the Product in each country in the Territory ("Pricing Guidelines") and the Detailing Percentage; (xi) discuss manufacturing and supply plans for the Product and delivery schedules; (xii) undertake the specific responsibilities set forth in ARTICLE IX; (xiii) resolve disputes concerning publication of Product Information (other than Legal Disputes [**********] (xiv) determine whether to designate any additional countries as Major Market Countries; (xv) allocate the supply of Finished Product in the Territory as provided in Section 8.8(c); (xvi) review and approve any increases to the Global Development Cap pursuant to Section 5.3(d)(i); (xvii) approve the methodology for determining whether a sales representative Details the Product in the primary, secondary or tertiary position; and (xviii) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties.

3.3 Joint Development Committee.

(a) Composition and Purpose. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the Development of the Product in the Field in the Territory; (ii) to review and implement the Initial Global Development Plan, and to develop (or oversee the development of), review and annually amend and present to the JSC for approval amendments to the Initial Global Development Plan, any Ex-U.S. Territory Development Plan and any amendments thereto (and related Development Budgets) for the Product; and (iii) to oversee the implementation of the Development Plans and the Development operational aspects of the Collaboration. The JDC shall be composed of three (3) senior executives of each Party; *provided that* the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). The JDC will have two (2) co-chairpersons, one designated by each of Regeneron and Teva.

(b) Specific Responsibilities. In particular, the JDC shall be responsible for the following activities with respect to the Product:

(i) advising the JSC on the overall Development strategy for the Product in the Field in the Territory;

(ii) developing (or overseeing the development of), and updating at least annually, the Development Plans (and related Development Budgets) for the Product in the Field in the Territory, for final approval by the JSC;

(iii) reviewing and overseeing the implementation of, and compliance with, the Development Plans (including the Development Budgets) for the Product in the Field in the Territory;

(iv) evaluating whether the Parties should Develop the Product for additional Indications in the Field in the Territory;

(v) overseeing clinical and regulatory matters pertaining to the Product in the Field arising from the Plans, and reviewing and approving protocols (including amendments thereto), statistical analysis plans, clinical trial plans (in terms of designs, endpoints, scales, sample sizes, study arms, doses, and duration), clinical methodology and monitoring requirements for clinical trials of the Product in the Field as contemplated under the Development Plans and for Non-Approval Trials;

(vi) reviewing results and data from ongoing clinical trials under a Development Plan, including ongoing enrollment and budgetary issues and ongoing safety, both protocol-specific and across the Development Plans;

(vii) reviewing (in coordination with the JCC) and approving the Company Core Data Sheet for the Product, and any changes thereto, and reviewing (in coordination with the JCC) and approving product labeling with respect to the Product in the Field in the Territory that deviates from the Company Core Data Sheet in accordance with Section 7.9;

(viii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of the Product in the Field in the Territory [**********];

(ix) formulating a life-cycle management strategy for the Product in the Field in the Territory;

(x) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Product in the Field [**********];

(xi) developing forecasts for Development Supply Requirements for the Territory;

(xii) reviewing (in coordination with the JCC) and approving the Common Technical Document, and any changes thereto, and any proposed submission of any Registration Filing in the Territory that does not conform to the Common Technical Document;

(xiii) reviewing and discussing strategies with respect to medical affairs for the Product to the extent not prohibited by applicable Law, including Non-Approval Trials, post-approval studies, educational materials and medical inquiries; and

(xiv) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.

3.4 Joint Commercialization Committee.

(a) Composition and Purpose. The purpose of the JCC shall be to develop and oversee the strategy for the Commercialization of the Product in the Field in the Territory, and to oversee the implementation of the Commercialization Plans and the Commercialization operational aspects of the Collaboration on a country-by-country basis in the Territory. The JCC shall be composed of at least two (2) senior executives of each Party having expertise and authority with respect to commercialization of products; *provided that* the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) JCC Responsibilities. In particular, the JCC shall be responsible for the following activities, which shall in each case be consistent with the applicable Commercialization Plans:

(i) developing and proposing to the JSC the strategy for the Commercialization of the Product in the Field in the Territory;

(ii) establishing the Regions and Reporting Country/Regions and establishing a Country/Region Commercialization Committee for each such Reporting Country/Region pursuant to Section 3.5;

(iii) developing (or overseeing the development of) and updating no less frequently than once per Calendar Year, the U.S. Commercialization Plan and related U.S. Commercialization Budget for final approval by the JSC;

(iv) commencing no later than [**********] prior to the Anticipated First Commercial Sale anywhere in the Ex-U.S. Territory (or

commencing as soon as reasonably practicable following the JSC's determination of the Anticipated First Commercial Sale in the event such determination is made within [**********] of the Anticipated First Commercial Sale), (A) developing (or overseeing the development of) and updating no less frequently than once per Calendar Year, the Ex-U.S. Territory Commercialization Plan and related Ex-U.S. Territory Commercialization Budget for final approval by the JSC; and (B) establishing, to the extent provided in Section 3.5, Country/Region Commercialization Committees to review and revise, and provide to the JSC for approval, Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any amendments thereto and carry out the other activities described in Section 3.5;

(v) defining target groups to be covered by overall marketing efforts in the applicable country, including key opinion leaders, physician groups, hospitals and regional buying groups, managed care organizations and governmental and government-affiliate buyers;

(vi) establishing the trade dress for the Product, consistent with the guidelines established by the JCC, in the applicable Major Market Country;

(vii) developing forecasts for Commercial Supply Requirements for the United States, and if applicable under the Commercial Supply Agreement, the Ex-U.S. Territory;

(viii) for the Product in the U.S., developing and updating, as necessary, the promotional guidelines for branding, positioning, core messages and Promotional Material messages and guidelines for determining the percentage of sales force compensation linked to sales of the Product in the U.S. (collectively, the items referred to in this paragraph (viii) shall be referred to as the "U.S. Marketing Guidelines") as part of the U.S. Commercialization Plan;

(ix) for the Product, on a country-by-country basis for the Major Market Countries in the Ex-U.S. Territory, developing and updating, as necessary, the Ex-U.S. Territory promotional guidelines for branding, positioning, core messages and Promotional Material messages and guidelines for determining the percentage of sales force compensation linked to sales of the Product in such country in the Ex-U.S. Territory (collectively, the items referred to in this paragraph (ix) shall be referred to as the "Ex-U.S. Territory Marketing Guidelines") as part of the Ex-U.S. Territory Commercialization Plan;

(x) for the Product in the Territory, developing and updating, as necessary, Territory-wide promotional guidelines for branding, positioning, core messages and Promotional Material messages (collectively, the items referred to in this paragraph (x) shall be referred to as the "Territory Marketing Guidelines"); *provided that* any inconsistency between the Ex-U.S. Territory Marketing Guidelines and the U.S. Marketing Guidelines shall be resolved in favor of the U.S. Marketing Guidelines and any inconsistency between the Ex-U.S. Territory Marketing Guidelines and the Territory Marketing Guidelines shall be resolved in favor of the Ex-U.S. Territory Marketing Guidelines;

(xi) reviewing and overseeing compliance with the U.S. Commercialization Plan (including the related U.S. Commercialization Budget), Ex-U.S. Territory Commercialization Plan (including the related Ex-U.S. Territory Commercialization Budget), and each Country/Region Commercialization Plans for the Product, including ensuring that the country specific launch plans are consistent with the applicable Marketing Guidelines, and reviewing and validating latest annual estimates for the current Calendar Year compared to the U.S. Commercialization Budget, Ex-U.S. Territory Commercialization Budget, and Country/Region Commercialization Budgets;

(xii) establishing the number and position of Details required to meet market and sales forecasts and their conversion into the equivalent number of FTEs for performance of such Details according to applicable weighting factors, based upon sales force and market practices on a country-by-country basis;

(xiii) establishing the methodology for determining whether a sales representative Details the Product in the primary, secondary or tertiary position for approval by the JSC;

(xiv) selecting the Product Trademark in accordance with Section 11.2 and giving guidance on trade dress for the Product;

(xv) determining the launch date for the Product on a country-by-country basis in the Territory;

(xvi) reviewing and recommending prices, discounts, rebate, reduction, chargeback and similar policies for the Product in the Major Market Countries and the European Union, which shall be consistent with the applicable Marketing Guidelines and Pricing Guidelines;

(xvii) preparing short-term and long-term sales forecasts for the Product on a country-by-country basis for Major Market Countries and reviewing such forecasts for the remaining countries;

(xviii) on a country-by-country basis in the Territory, (A) preparing a strategy for Non-Approval Trials, (B) overseeing the design of such trials, and (C) determining which such trials should be conducted, rejected or redesigned and whether any such trials should be referred to the JDC for consideration for inclusion in the applicable Development Plan;

(xix) validating the contents, design and layout of packaging for the Product in the Field in the Territory;

(xx) validating plans and policies regarding journal and other publications with respect to the Product in the Field in the Territory in concert with the JDC;

(xxi) formulating a life-cycle management strategy for the Product in the Field in the Territory and evaluating new opportunities for new Indications;

(xxii) discussing matters relating to the Parties' respective Co-Promote Commitment Level with respect to the Product in the U.S.;

(xxiii) reviewing (in coordination with the JDC) the Common Technical Document and Company Core Data Sheet for the Product, and any changes thereto, and reviewing (in coordination with the JDC) any product labeling with respect to the Product in the Field in the Territory that deviates from the Company Core Data Sheet in accordance with Section 7.9; and

(xxiv) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the JSC or JDC.

3.5 Reporting Country/Regions; Country/Region Commercialization Committees. The JCC will establish the Regions and Reporting Country/Regions in the Ex-U.S. Territory, and for each Reporting Country/Region, as determined by the JCC, the JCC will establish one or more Country/Region Commercialization committees (each, a "Country/Region Commercialization Committee" or "CRCC") as and when determined by the JCC. The Country/Region Commercialization Committees will be responsible for reviewing and revising the Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) prepared and submitted by Teva (with Regeneron's meaningful participation and input) and any amendments thereto with respect to the applicable Reporting Countries/Region(s) and submitting

the foregoing to the JCC. The Country/Region Commercialization Committees will also serve as a forum to consider and discuss and, if so empowered by the JCC, decide, in a more detailed and focused manner with respect to the applicable Reporting Countries/Region(s), and make suggestions or recommendations to the JCC with respect to, the matters referred to in Section 3.4, as applicable, including the implementation of decisions with respect thereto made by the JCC as contemplated by this Section 3.5.

3.6 Joint Finance Committee. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including (a) reviewing the Global Development Budget, Ex-U.S. Territory Development Budget, U.S. Commercialization Budget, Ex-U.S. Territory Commercialization Budget, each Country/Region Commercialization Budget and any budget contained within the Development Proposal under Section 5.3 and advising and consulting with the JDC, JPSC, JCC or JSC with respect to all such budgets as well as Development Overruns and Commercialization Overruns; *provided*, that the JFC shall not have any input regarding conduct or inclusion of any activities in any of the foregoing Plans, (b) discussing the reports delivered pursuant to Section 5.3(e), (c) determining whether to have an FTE rate that is different than the Development FTE Rate for contractors performing Development activities under this Agreement, in lieu of charging the activities of such contractors as Out-of-Pocket Costs; (d) determining whether to have a different Field Force FTE Rate for sales representatives that Detail different Healthcare Prescribers; (e) determining an appropriate separate indexed adjustment mechanism for adjusting any FTE Rate for personnel located outside the United States; (f) determining the applicable Field Force FTE Rate for each category of Field Force Personnel; (g) such specific responsibilities set forth in ARTICLE IX; (h) [**********]; and (i) considering and acting upon such other matters as specifically assigned to the JFC under this Agreement or by the JSC. The JFC also shall respond to inquiries from the JSC, the JDC, the JPSC and the JCC, as needed. The JFC shall be initially composed of two (2) senior executives, directors or general managers of each Party; *provided that* the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

3.7 Joint Product Supply Committee. Working with the JSC, JDC, JCC and JFC, as appropriate, the JPSC shall be responsible for overseeing certain matters relating to the supply of the Product for the United States and to Teva, its Affiliates or its or their Distributor/Commercial Partners in the Ex-U.S. Territory, including (a) Product supply forecasts, (b) safety stock requirements, (c) adoption of Manufacturing Process Improvements for the Product in the Territory, (d) the need for and implementation of recalls, market withdrawals or any other corrective actions related to the Product in the Territory, (e) reviewing contract manufacturing agreements for the Product [**********], (f) discussing any Ex-U.S. Territory Product Changes and (g) considering

and acting upon any other matters specifically assigned to the JPSC by the JSC; [**********]. The JPSC shall be initially composed of two (2) senior executives, directors or general managers of each Party; *provided that* the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

3.8 Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Teva, with each representative having the requisite experience and seniority to enable such person to make decisions on behalf of such Party with respect to the issues falling within the jurisdiction of such Committee. Each Party may replace its Committee members upon written notice to the other Party; *provided that* such replacement has the foregoing requisite experience and seniority; and *provided, further*, that the Committee composition meets the requirements of this ARTICLE III. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Teva, and each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities, including with respect to the JSC, with their respective Alliance Manager (as contemplated by Section 3.12), to prepare and circulate an agenda in advance of each meeting and prepare and issue final minutes within [**********] thereafter.

3.9 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than [**********] during the Term, commencing from and after the time such Committee is established as provided herein unless the co-chairpersons agree otherwise. All Committee meetings may be conducted by telephone, video-conference or in person as determined by mutual agreement of the co-chairpersons; *provided that* each Committee shall meet in person at least once each Calendar Year, unless the Parties mutually agree to meet by alternative means; *provided further* that, unless otherwise agreed by the Parties, the JDC shall meet at least [**********]. Unless otherwise agreed by the Parties, all in-person meetings of a Committee shall be held on an alternating basis between Regeneron's facilities and Teva's facilities. Further, in addition to the regularly scheduled quarterly meetings, a Committee shall meet upon the reasonable request of the co-chairpersons or either Party's co-chairperson, as applicable. A reasonable number of other employees of a Party (including Alliance Managers) may attend any Committee meeting as non-voting observers, including in the case of the JDC, employees of each Party with expertise in the fields of clinical development; pharmacovigilance; biostatics; general clinical operations; regulatory operations; and medical affairs; *provided that* such additional employees are under obligations of confidentiality and non-use applicable to the confidential information of the other Party that are at least as stringent as those set forth in ARTICLE XVI. In addition, other representatives of each Party or of Third Parties involved in the Development or Commercialization of the Product in the Field may be invited by the mutual agreement of the Committee co-chairpersons to attend meetings of the Committees as nonvoting participants; *provided that* such other representatives are under obligations of confidentiality and non-use

applicable to the confidential information of the other Party that are at least as stringent as those set forth in ARTICLE XVI. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least [**********] prior written notice, except that emergency meetings may be called with at least [**********] prior written notice. Any alternative agreement of the Parties or the applicable co-chairpersons with respect to Committee meetings under this Section 3.9 shall be in writing.

3.10 Decision-Making; Authority. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; *provided that* no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. The Committees shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on such Committee are given due consideration.

3.11 Resolution of Committee Matters.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible; *provided that*, in the case of any matter that cannot be resolved by the JDC, the JCC, the JFC, any CRCC, or other relevant Committee established hereunder, at the written request of either Party, such matter shall promptly, and in any event within [**********] (or [**********] in the event of an urgent matter) after such request, be referred to the JSC with a written request for resolution.

(b) Unresolved Matters. The JSC shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on the JSC are given due consideration. In the event that the JSC is, after a period of [**********] from the date a matter is submitted in writing to it for resolution pursuant to Section 3.11(a), unable to make a decision due to a lack of consensus between the representatives of Regeneron on such Committee, on the one hand, and of Teva, on the other hand (any such matter, an "Unresolved Matter"), then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. If the Executive Officers are not able to resolve any Unresolved Matter pertaining to [**********], such dispute shall be a "Legal Dispute" and resolved in accordance with Section 10.3. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within [**********] (or, in the case of a Legal Dispute, [**********] of receiving such written notification, failing which, unless such matter is a Financial Dispute (in which case it shall be resolved in accordance with Section

3.11(c) and Section 10.4) or a Termination Dispute (in which case it shall be resolved in accordance with Section 19.2(b)) or a Legal Dispute (in which case it shall be resolved in accordance with Section 10.3), either Regeneron's Executive Officer or Teva's Executive Officer shall, except as otherwise expressly set forth in this Agreement, have final decision-making authority with respect to such Unresolved Matter as follows:

(i) The Executive Officer of Regeneron shall have final decision-making authority with respect to Unresolved Matters pertaining to [**********]

(ii) Except as otherwise provided in Section 19.5, the Executive Officer of Teva shall have final decision-making authority with respect to Unresolved Matters pertaining to[**********];

provided that:

(A) in no event may Teva exercise its final decision-making authority in a manner that [**********];

(B) in no event may Regeneron exercise its final decision-making authority to [**********] (such portion in excess of such Global Development Cap, the "Budget Cap Overage");

(C) Regeneron may not exercise its final decision-making authority to [**********], and Regeneron may not exercise its final decision-making authority to [**********];

(D) in no event may a Party exercise its final decision-making authority [**********];

(E) in no event may a Party exercise its final decision-making authority in a manner that the other Party reasonably believes raises material concerns that such second Party could be in violation of applicable Law; in no event shall either Party have final decision-making authority with respect to any Unresolved Matter that constitutes a Legal Dispute or a Financial Dispute or a Termination Dispute. Any Unresolved Matter constituting a Financial Dispute shall [**********] pursuant to Section 3.11(c) and Section 10.4, any Unresolved Matter constituting a Legal Dispute shall be resolved as provided in Section 10.3, and any Unresolved Matter constituting a Termination Dispute shall be resolved as provided in Section 19.2(b); and

(F) in no event shall either Party have final decision-making authority with respect to[**********].

(c) Financial Disputes. In the event that the Executive Officers are, after a period of[**********] from the date a matter is referred to them for resolution pursuant to Section 3.11(b), unable to resolve a dispute with respect to any matter initially before the JFC regarding accounting, financial (including reporting and controls), or funds flow matters under this Agreement, including any dispute relating to a Quarterly True-Up Report for a Quarter or any payment due thereunder, but, for clarity, not including any dispute regarding any budget for any Plan or matter relating to the conduct or inclusion of any activities in a Plan, even if such dispute may affect the budget for any such Plan, or any Legal Dispute (a "Financial Dispute"), then such matter shall be referred to the Financial Disputes resolution procedures set forth in Section 10.4; *provided that* any such dispute resolved by an independent audit pursuant to Section 14.2 shall not be considered a "Financial Dispute" hereunder for purposes of ARTICLE X.

3.12 Alliance Management. Each of Teva and Regeneron shall appoint a senior representative who possesses a general understanding of this Agreement and pharmaceutical research, clinical, regulatory, manufacturing and commercialization issues to act as its Alliance Manager ("Alliance Manager"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties to assure a successful Collaboration and to facilitate resolution of deadlocks or disputes that may arise. Each Alliance Manager will also be responsible for being the primary point of communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization and for the sharing of information and responding to information requests between Committee meetings. Each Alliance Manager will manage the governance process for its respective Party, including attendance at, and facilitating, the JSC meetings as a non-voting member and the Alliance Managers together shall be responsible for any JSC meeting agendas and materials and provide such agendas and materials at least [**********] in advance of such meeting and prepare and circulate to the JSC members and the JSC minutes of each JSC meeting within [**********] thereof. Each Alliance Manager shall be included as an invitee for each Committee and Working Group meeting required thereunder (with such Alliance Manager's attendance determined on an agenda driven basis). A Party may change its Alliance Manager by providing written notice to the other Party thereof.

3.13 Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any

of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement that restricts or prohibits a Party from taking any specified action.

3.14 Exchange of Information. Each of Regeneron and Teva will provide regular and fulsome updates to the other Party, through the JSC or the applicable Committee, with respect to all activities undertaken by or on behalf of such Party under the Collaboration. Without limiting the foregoing, during the Term, each of Regeneron and Teva will promptly notify the other Party of any material information regarding the Development or Commercialization of the Product, including any material correspondence with a Governmental Authority, and each Party shall provide the other Party with such information regarding the Collaboration that the other Party may reasonably request. **********].

ARTICLE IV
APPOINTMENT OF DISTRIBUTORS AND SUBCONTRACTORS

4.1 Distributor/Commercial Partners. If Teva desires to appoint a Distributor/Commercial Partner to market or distribute the Product (including to co-market or co-distribute the Product with Teva) in one (1) or more countries the Ex-U.S. Territory, then Teva shall notify Regeneron, and upon such notice the Parties shall discuss in good faith the qualifications of such proposed Distributor/Commercial Partner and whether and under what conditions Regeneron would grant to Teva the right to use such Distributor/Commercial Partner(s) to market or distribute the Product in such country(ies). Without limitation of the foregoing, any Distributor/Commercial Partner agreement will include an obligation of such Distributor/Commercial Partner to account for and report its sales of the Product to the Party appointing such Distributor/Commercial Partner on the same basis as required of such appointing Party. Teva shall not appoint a Distributor/Commercial Partner [**********]. Subject to Section 6.7, any appointment of any Distributor/Commercial Partner by Regeneron to market or distribute the Product (including to co-market or co-distribute with Product with Teva) in the United States shall require [**********] and this Section 4.1 shall apply *mutatis mutandis* with respect thereto. If either Party appoints a Distributor/Commercial Partner to market or distribute the Product (including to co-market or co-distribute the Product with the other Party) such Party shall remain responsible and liable for the acts and omissions of such Distributor/Commercial Partner.

4.2 Subcontractors. Subject to Section 4.1, each Party shall have the right to contract with one or more Third Parties to perform certain of its obligations under the Plans and

any Additional Trial Plans if specifically contemplated therein; *provided that* (a) the subcontracting Party shall remain responsible and liable for the acts and omissions of such Third Party service providers, (b) such Third Parties undertake in writing obligations of confidentiality and non-use of Product Information and Party Information that are substantially the same (no less stringent than) as those undertaken by the Parties under this Agreement and (c) such Third Parties undertake in writing obligations to assign to such Party any intellectual property (including Know-How, Patents and copyrights) (other than such Third Party's background intellectual property that is not specifically related to (x) any Competing Product (including the Product) (including any component or intermediate thereof) or (y) the exploitation (including any method of Manufacture [**********], or method of treatment or other use) of any Competing Product (including the Product)) discovered, invented, authored or otherwise created under or in connection with any performance of such Party's obligations under the applicable Plan or Additional Trial Plan.

4.3 Additional Terms Applicable to Distributor/Commercial Partners and Subcontractors.

(a) In the event of a breach by a Distributor/Commercial Partner or subcontractor of any agreement entered into between a Party or any of its Affiliates and such subcontractor or Distributor/Commercial Partner as contemplated by this Agreement, that has, or is reasonably likely to have, an adverse effect on the other Party or any of its Affiliates, then such other Party may cause the contracting Party or its Affiliate to exercise, and such other Party or its Affiliate will promptly exercise, any termination or other rights it may have under the agreement with the Distributor/Commercial Partner or subcontractor with respect to such breach. Without limitation of Section 4.1 or Section 4.2, any agreement entered into after the Effective Date between Teva or any of its Affiliates with a Distributor/Commercial Partner or subcontractor in performance of this Agreement will provide for the termination of the agreement or the conversion of the agreement to an agreement directly between the Distributor/Commercial Partner or subcontractor and Regeneron, at the option of Regeneron, upon termination of this Agreement. Furthermore, any subdistribution agreement or subcontract to which a Party or any of its Affiliates is a party with respect to the Product or the Development, Manufacture or Commercialization thereof in the Territory shall prohibit any further subdistribution, subcontracting or assignment.

(b) For the avoidance of doubt, [**********].

ARTICLE V
DEVELOPMENT ACTIVITIES

5.1 Development of the Product. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to the Product in the Field for use in

the Territory pursuant to and in conformance with the applicable Development Plans under the general direction and oversight of the JSC.

(a) Each Party shall (i) use Commercially Reasonable Efforts to Develop the Product for use in the Field pursuant to the terms of this Agreement and carry out the Development activities assigned to it in Development Plans in a timely manner and (ii) conduct all such Development activities hereunder in compliance with applicable Laws, including, Good Practices.

(b) Without limitation of Section 5.1(a), [**********]: (i) Teva shall, through the JDC and in consultation with Regeneron, develop and present to the JSC for review and approval a [**********] plan for Development that is required to support Approval of the Product in [**********], which plan must be presented to the JSC by the date that is [**********] from the Effective Date (which plan upon approval by the JSC shall constitute part of the Ex-U.S. Territory Development Plan); and (ii) [**********], Teva shall commence performance of the activities in accordance with the Ex-U.S. Territory Development Plan that are solely required to support Approval of the Product in [**********] by the [**********] anniversary of the Effective Date.

5.2 Development Principal Party. Unless and to the extent otherwise agreed by the Parties with respect to the Product, subject to the proviso in the third sentence of Section 5.4(a) and Section 7.1, Regeneron shall be the Development Principal Party for all Development of the Product (including with respect to developing and implementing trial protocols, sponsoring clinical trials, collecting data, and providing MSL support for clinical trials in the U.S.), except that, subject to the proviso in the third sentence of Section 5.4(a) and Section 7.1, Teva shall be the Development Principal Party with respect to any Development [**********] (a) in the Ex-U.S. Territory that is required solely to support Approval of the Product in the Field in the Ex-U.S. Territory and (b) with respect to any Teva Additional Trials. Notwithstanding the foregoing, after the Marketing Approval of the Product in a country or region, as applicable, in the Ex-U.S. Territory, Regeneron may cease any open label extension in such country or region of any clinical trial conducted under the Global Development Plan; [**********]. Teva shall not conduct any non-clinical Development of the Product except to the extent set forth in the Ex-U.S. Territory Development Plan and unless Regeneron elects not to conduct such non-clinical Development. Regeneron may perform Development activities outside the Territory to support Development of the Product for the Territory under the Global Development Plan or a Regeneron Additional Trial Plan.

5.3 Development Plans and Development Budgets. The JDC shall develop (or oversee the development of) and update Development Plans for the Product in the Field in the Territory under this Agreement for approval by the JSC.

(a) Global Development Plan. Consistent with the Collaboration Purpose, the Global Development Plan shall include those Development activities necessary to be undertaken for the Product to achieve [**********]. Except for the Initial Global Development Plan, an updated Global Development Plan will be presented at least [**********] prior to the end of each Calendar Year (starting in 2017) by the JDC to the JSC for review and approval at least [**********] prior to the end of each Calendar Year. Each Global Development Plan will set forth, in a reasonable level of detail, the plan for Development of the Product in the Field in the Territory over at least [**********] and will include strategies and timelines for Developing and obtaining and maintaining Approvals for the Product in the Field in the United States and in the Territory except with respect to Development under the Ex-U.S. Territory Development Plan. Each Global Development Plan shall be consistent with the Collaboration Purpose. If Teva wishes for Regeneron to conduct under the Global Development Plan any Development activities that are required to receive Marketing Approval or Pricing Approval for a Product for a Set Indication in a Major Market Country other than the United States that would otherwise be Ex-U.S. Development Activities, then Teva shall so notify Regeneron and Regeneron shall include such Development activities under the Global Development Plan [**********] unless Regeneron reasonably believes in good faith that the conduct of such Development activities by Regeneron under the Global Development Plan (A) would have a material negative effect on (1) the overall Development strategy or Development timeline for, or the Commercialization of, the Product (including if the foregoing would result from a material impact on the supply of the Product contemplated by clause (C) below), or (2) the overall commercial viability of the Product, including the magnitude of sales for the Product, (B) would materially delay or have a material negative effect on any Registration Filing or the receipt of any Approval for the Product, or (C) would create an unreasonable burden on Regeneron's ability to supply the Development Supply Requirements or the Commercial Supply Requirements.

(b) Ex-U.S. Territory Development Plan. No later than [**********] after the Effective Date, the JDC shall develop and present an initial Ex-U.S. Territory Development Plan to the JSC for review and approval. Each Ex-U.S. Territory Development Plan will set forth, in a reasonable level of detail, the plan for any Development of the Product that is required solely to obtain and maintain Approvals for the Product in the Field in the Ex-U.S. Territory over at least [**********] and will include strategies and timelines for Developing and obtaining and maintaining such Approvals. Each Ex-U.S. Territory Development Plan shall be consistent with the Global Development Plan and Collaboration Purpose. Regeneron shall not be responsible for any activities under the Ex-U.S. Territory Development Plan or any Teva Additional Trial Plan unless otherwise agreed in writing by the Parties, except that Regeneron shall perform non-clinical activities under the Ex-U.S. Territory Development Plan or any Teva Additional Trial Plan that are required by a Regulatory Authority in the Territory, and further, Regeneron may not unreasonably withhold, condition or delay its agreement to perform any non-clinical Development activities under the Ex-

U.S. Territory Development Plan or Teva Additional Trial Plan (even if not so required by a Regulatory Authority); *provided that* in lieu of Regeneron performing any such non-clinical Development activities, Regeneron may, at Regeneron's election, enable Teva to do so upon Teva's request.

(c) Amendments to the Development Plans. Either Party may propose at any meeting of the JDC updates or amendments to a Development Plan and corresponding Development Budget; *provided that* if any updates or amendments proposed by a Party or the JDC under this Agreement involve or otherwise relate to a Proposed New Indication or Proposed Combination Therapy or to an [**********], the inclusion thereof shall be subject to and in accordance with Section 5.4 and corresponding Sections referenced therein. Each such Development Plan will be reviewed by the JDC not less frequently than once every [**********] for the ensuing [**********] period, and an amended Global Development Plan and an amended Ex-U.S. Territory Development Plan will be presented by the JDC to the JSC for review and approval following any material updates thereto (including with respect to any Development Proposal approved by the JSC for inclusion under a Development Plan as contemplated by Section 5.4), and in any event, will be presented at least [**********] prior to the end of each Calendar Year (starting in 2017) by the JDC to the JSC for review and approval at least [**********] prior to the end of each Calendar Year.

(d) Development Budgets.

(i) Notwithstanding anything to the contrary herein (including Section 3.10 and Section 3.11), any and all amendments or modifications to the Global Development Cap shall require the mutual written agreement of both Parties; *provided*, *however*, that the Global Development Cap shall automatically be amended[**********].

(ii) Each Global Development Plan for the Product shall include a related Global Development Budget, which, for the clinical trials for the Set Indications and any Selected Combination Therapy, shall be consistent with the Global Development Cap, and each Ex-U.S. Territory Development Plan shall include a related Ex-U.S. Territory Development Budget and be submitted to the JSC for review and approval simultaneously with submission of the applicable Development Plan. Each Development Budget shall provide for [**********] funding for the Development of the Product in accordance with this Agreement. The JDC shall have the right to submit amendments for such Development Budgets to the JSC for review and approval in accordance with this Agreement. No Development Budget or any amendment thereto shall be effective without the approval of the JSC; *provided that* no amendment shall be made to the Global

Development Budget for a Calendar Year during such Calendar Year [**********] unless and to the extent such amendment is the result of changes to the Global Development Plan or is the result of circumstances outside the control of Regeneron and necessary for Approval of the Product in the United States or both inside and outside the United States for any Set Indication or Selected Combination Therapy under the Global Development Plan.

(e) Development Reports. Within [**********] after the end of each Quarter, Regeneron and Teva shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with (i) in the case of Regeneron, the Global Development Plan and (ii) in the case of Teva, the Ex-U.S. Territory Development Plan, in each case ((i) and (ii)), together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall be in such form, format and of such level of detail as approved by the JFC, and any Additional Trials (with a statement of Additional Trial Costs incurred by such Party during such Quarter) conducted by or on behalf of such Party.

5.4 Additional Trials.

(a) Proposal and Election of Additional Trials. If a Party desires that the Parties undertake in the Territory any additional clinical trial and supporting Development of the Product in the same formulation(s), [**********], as the Product is being Developed under the Global Development Plan or a Regeneron Additional Trial Plan [**********] that is not contemplated in the current applicable Development Plan, then such Party shall present a proposal to the JSC outlining the proposed protocol, clinical trial design and additional Development activities to be conducted thereunder along with a proposed budget for such additional activities (such new Indication a "Proposed New Indication", such combination therapy a "Proposed Combination Therapy" and such proposal, a "Development Proposal"). Unless otherwise agreed by the Parties, no clinical trials or supporting Development of the Product that are within the scope of the definition of "Ex-U.S. Territory Development Activities" shall be included in any Development Proposal of, or Additional Trial conducted by, Teva. If (1) the applicable Party presents such Development Proposal to the JSC in accordance herewith, and (2) the JSC fails [**********] to approve such Development Proposal for inclusion under the applicable Development Plan within [**********] of the date such Development Proposal is presented to the JSC, then such Party, may, at its option and at its sole cost and expense, subject to this Section 5.4(a), conduct and control such additional clinical trial(s) and supporting Development of the Product for such Proposed New Indication or Proposed Combination Therapy in the Territory outside the scope of the applicable Development Plan upon written notice to the other Party (such conducting Party, the "Conducting Party," any

such clinical trial and corresponding Development so elected, an "Additional Trial," and any such Proposed New Indication or Proposed Combination Therapy that is the subject of such Additional Trial an "AT Indication" or "AT Combination Therapy," respectively) subject to the terms and conditions of this Section 5.4; [**********]. If the JSC elects (x) [**********] to include such Development Proposal under a Development Plan as contemplated above, or (y) [**********], then in each case, the JDC shall promptly amend and update (and submit to the JSC for review and approval) the applicable Development Plan and corresponding Development Budget to include such Selected Global Indication or Selected Combination Therapy or Development Proposal, as applicable thereunder; *provided that* any such amendments to the Global Development Budget shall be subject to Section 5.3(d); *provided*, *further*, if such inclusion under the Global Development Plan results in [**********]. For clarity, notwithstanding [**********], if the then-current Global Development Cap has not been exceeded, [**********].

(b) Additional Trial Plan. Following its election to conduct an Additional Trial pursuant to Section 5.4(a), the Conducting Party must first present an Additional Trial Plan, and any further material amendments thereto, to the other Party's representatives on the JSC for approval, [**********]. The Non-Conducting Party may disapprove the conduct of an Additional Trial outside the relevant Development Plan, or any such protocols or clinical trial designs, or any amendments thereto, solely (i) for bona fide serious health or safety concerns or (ii) if the Non-Conducting Party reasonably believes in good faith that the conduct of such Additional Trial [**********]. If the Non-Conducting Party disapproves the conduct of the proposed Additional Trial outside of the applicable Development Plan (or any amendment to the plan therefor) in accordance with this Section 5.4(b), the Conducting Party may not proceed with the proposed Additional Trial (or amend the Additional Trial Plan therefor); *provided that* if the Conducting Party disputes such disapproval, such dispute shall be referred to the Executive Officers for resolution. If the Executive Officers are not able to resolve such dispute, then such dispute shall be a "Legal Dispute" and resolved in accordance with Section 10.3.

(c) Results. In the event that either Party conducts an Additional Trial, (i) the Conducting Party shall promptly disclose to the Non-Conducting Party a summary of the results and data generated in or arising from any such Additional Trial upon completion of such Additional Trial, (ii) ownership of Know-How (including results and data) and Patents generated in or arising from any such Additional Trial shall be subject to the ownership provisions of ARTICLE XII and (iii) such data and results shall be subject to publication in accordance with ARTICLE XVI. The Conducting Party shall also provide to the Non-Conducting Party any drug safety data from such Additional Trials in accordance with Section 7.4 or the Safety Data Exchange Agreement and any other information specifically requested by a Regulatory Authority to enable the Non-Conducting Party to fulfill its regulatory obligations with respect to the Product.

(d) Funding. If the Non-Conducting Party approves an Additional Trial in accordance with Section 5.4(b), such Additional Trial shall be funded at the Conducting Party's sole cost and expense, which cost and expense shall not be shared by the Parties except as provided in Section 9.2(c). The Conducting Party shall keep records associated with Additional Trial Costs incurred through performance of the Additional Trial separate from records associated with Development Costs incurred through performance under a Development Plan.

ARTICLE VI
COMMERCIALIZATION

6.1 Commercialization of the Product in the Field in the Territory.

(a) Generally. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to the Product in the Field in the Territory under the direction and oversight of the JCC. With respect to the Product in the United States, Regeneron shall be the Lead Commercialization Party, and with respect to the Product in the Ex-U.S. Territory, Teva shall be the Lead Commercialization Party. Each Party shall ensure that its Commercialization activities conform to the applicable approved Commercialization Plans. The following provisions shall apply with respect to such Commercialization activities.

(b) Commercialization of the Product in the U.S. Regeneron and Teva shall use Commercially Reasonable Efforts to Commercialize the Product in the Field in the U.S. and shall do so in compliance with applicable Laws and the applicable Marketing Guidelines and Pricing Guidelines. Each Party shall initially bear all costs and expenses in connection with its Co-Commercialization of the Product in the Field in the United States; *provided that* to the extent such costs and expenses constitute Shared Commercial Expenses they will be shared by the Parties through the Shared Commercial Expenses True-Up mechanism set forth in Schedule 3.

(c) Commercialization of the Product in the Ex-U.S. Territory. Teva shall use Commercially Reasonable Efforts to Commercialize the Product in the Ex-U.S. Territory and shall do so in compliance with applicable Laws and the applicable Marketing Guidelines and Pricing Guidelines. Except as otherwise provided in this Agreement, Teva shall bear all costs and expenses in connection with the Commercialization of the Product in the Field in the Ex-U.S. Territory.

6.2 Commercialization Plans.

(a) U.S. Commercialization Plan. The JCC shall develop the U.S. Commercialization Plan, including the U.S. Commercialization Budget therefor. The U.S. Commercialization Plan and all amendments thereto will be consistent with the Collaboration Purpose. The U.S. Commercialization Plan shall be presented to the JSC for review and approval

within [**********] of the Effective Date. An amended U.S. Commercialization Plan shall be presented at least [**********] prior to the end of each Calendar Year (starting in 2017) by the JCC to the JSC for review and approval at least [**********] prior to the end of the Calendar Year. The U.S. Commercialization Plan shall be consistent with the Global Development Plan and the Collaboration Purpose. The U.S. Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale in the U.S., to enable the JCC and the JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(i) the overall strategy for Commercializing the Product in the Field in the U.S., including the size of the sales forces, target product profiles, branding, positioning, promotional materials and core messages for the Product;

(ii) the allocation of Commercialization activities between each of Regeneron and Teva;

(iii) the targets for Details by each Party, including the Target Healthcare Prescribers for each Party;

(iv) the Pricing Guidelines for the Product in the Field in the U.S.;

(v) the related U.S. Commercialization Budget;

(vi) anticipated launch date for the Product in the U.S. and anticipated and expected dates for subsequent Indication Approvals;

(vii) market and sales forecasts for the Product in the Field in the U.S. in a form to be agreed between the Parties;

(viii) strategies for the detailing and promotion of the Product in the Field in the U.S.;

(ix) anticipated major advertising, public relations and patient advocacy programs for the Product in the Field in the U.S.;

(x) forecasts for Commercial Supply Requirements in the U.S.;

(xi) Non-Approval Trials in the U.S.;

(xii) all other U.S. Marketing Guidelines;

(xiii) the Co-Promote Commitment Level of each Party and additional detailed information on the coordination of detailing and promotional efforts and the specific allocation of Co-Promotion efforts between the Parties; and

(xiv) Commercialization activities managed on a Territory-wide basis that are intended to benefit Commercialization of the Product in the United States and the Ex-U.S. Territory (the "Global Commercialization Activities").

(b) Ex-U.S. Territory Commercialization Plan. Teva, with Regeneron's meaningful participation and input, shall prepare and submit the Ex-U.S. Territory Commercialization Plan to the JCC for review and approval by the JSC, including the Ex-U.S. Territory Commercialization Budget therefor. The Ex-U.S. Territory Commercialization Plan and all amendments thereto will be consistent with the U.S. Commercialization Plan, the Global Development Plan, the Ex-U.S. Territory Development Plan, and the Collaboration Purpose. The Ex-U.S. Territory Commercialization Plan shall be presented to the JSC for review and approval at least [**********] before the Anticipated First Commercial Sale in the Ex-U.S. Territory of the Product. An amended Ex-U.S. Territory Commercialization Plan shall be presented at least [**********] prior to the end of each Calendar Year by the JCC to the JSC for review and approval at least [**********] prior to the end of the then-current Calendar Year. The Ex-U.S. Territory Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale in the Ex-U.S. Territory, to enable the JCC and the JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

(i) the overall strategy for Commercializing the Product in the Field in the Ex-U.S. Territory, including target product profiles, branding, positioning, promotional materials and core messages for the Product;

(ii) Pricing Guidelines for the Product in the Field in the Ex-U.S. Territory;

(iii) the related Ex-U.S. Territory Commercialization Budget;

(iv) anticipated launch date for the Product in each Major Market Country and Reporting Country/Region in the Ex-U.S. Territory and anticipated and expected dates for subsequent Indication Approvals;

(v) market and sales forecasts for the Product in the Field in the Ex-U.S. Territory in a form to be agreed between the Parties;

(vi) forecasts for Commercial Supply Requirements in the Ex-U.S. Territory;

(vii) strategies for the detailing and promotion of the Product in the Field in the Ex-U.S. Territory;

(viii) anticipated major advertising, public relations and patient advocacy programs for the Product in the Field in the Ex-U.S. Territory;

(ix) Non-Approval Trials in the Ex-U.S. Territory; and

(x) all other Ex-U.S. Territory Marketing Guidelines.

(c) Country/Region Commercialization Plans. Each Country/Region Commercialization Plan for the Product, and all amendments thereto, will be consistent with the Ex-U.S. Territory Commercialization Plan, the U.S. Commercialization Plan, the Global Development Plan, the Ex-U.S. Territory Development Plan, and the Collaboration Purpose. It is anticipated that each Country/Region Commercialization Plan and the Country/Region Commercialization Budget for the Product for each Reporting Country/Region in the Ex-U.S. Territory will be prepared by Teva, with Regeneron's meaningful participation and input, and submitted to the applicable Country/Region Commercialization Committee at least [**********] before the Anticipated First Commercial Sale anywhere in the applicable Reporting Country/Region. The Parties shall ensure that the applicable Country/Region Commercialization Committee promptly submits such Country/Region Commercialization Plan and corresponding Country/Region Commercialization Budget to the JCC for review and revision and that the JCC promptly submits such Country/Region Commercialization Plan and corresponding Country/Region Commercialization Budget to the JSC for review and approval, in each case, so that they are approved by the JSC no later than [**********] prior to Anticipated First Commercial Sale anywhere in the applicable Reporting Country/Region. Such Country/Region Commercialization Plan for each subsequent Calendar Year shall be amended by Teva, with Regeneron's meaningful participation and input, and submitted to the applicable Country/Region Commercialization Committee. The Parties shall ensure that the applicable Country/Region Commercialization Committee promptly submits such amended Country/Region Commercialization Plan and corresponding Country/Region Commercialization Budget to the JCC for review and revision and that such amended Country/Region Commercialization Plan and corresponding Country/Region Commercialization Budget is presented at least [**********] prior to the end of each Calendar Year by the JCC to the JSC for review and approval at least [**********] prior to the end of the then-current Calendar Year. Each Country/Region Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including,

subject to the Ex-U.S. Territory Commercialization Plan, the overall strategy for Commercializing the Product, pricing strategies, and market and sales forecasts.

6.3 Commercialization Efforts; Sharing of Commercial Information.

(a) Without limitation of Section 6.1, the Parties (through their respective Affiliates where appropriate) shall use Commercially Reasonable Efforts to carry out the activities assigned to it in the applicable Commercialization Plan(s) in a timely manner. Without limiting the generality of the foregoing, (i) Teva, with respect to the Product in the Ex-U.S. Territory, and (ii) Regeneron and Teva, with respect to the Product in the U.S. will, as necessary, (A) build, train and apply Field Force Personnel necessary to Commercialize the Product in the Field in accordance with the applicable Commercialization Plans and all applicable Laws, and (B) cause its respective Field Force Personnel in such countries to provide the FTE effort and to Commercialize the Product in the Field in accordance with the approved Commercialization Plans and all applicable Laws.

(b) Each Party will make available, upon reasonable request of the other Party and to the extent reasonably available, material information directly relating to the Commercialization of the Product in the Field in the Territory, including, information relating to anticipated launch dates, key market metrics, market research, and sales; [**********].

(c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Product in the Field in the Territory, Product quality complaints and similar information.

(d) No Party may initiate or support any Non-Approval Trial for the Product in the Field in the Territory without the prior approval of the JSC.

6.4 Co-Commercialization of the Product.

(a) Field Force Coordination. The JCC or the applicable Committee shall coordinate the Co-Promotion of the Product in the U.S. by (i) Regeneron and its local Affiliates and their respective field forces, on the one hand, and (ii) Teva and its local Affiliates and their respective field forces, on the other hand. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, and professional or other customer targeting in accordance with the approved U.S. Commercialization Plan. Without limiting the generality of the foregoing, the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted to the extent necessary. Regeneron shall have the sole right to field NAMs and MSLs in the U.S.; *provided that* Regeneron shall permit and enable Teva's meaningful participation with respect to the strategy therefor through the JCC.

(b) FTE Efforts. The U.S. Commercialization Plan will set forth the number of FTEs that each Party commits to Co-Promoting the Product in the U.S. with respect to its respective Target Healthcare Prescribers (the "Co-Promote Commitment Level"), which shall be based upon and consistent with the forecasted number and position of Details required to meet the market and sales forecasts for the Product in the United States as set forth in the applicable U.S. Commercialization Plan.

(c) Training. The Parties will coordinate their training efforts with respect to their Field Force Personnel in the U.S. and will share training materials (and conduct joint training, where appropriate) to facilitate joint Field Force Personnel training efforts. Each Party shall be responsible, at its own cost and expense, for training any other individual actively involved in the Commercialization of the Product in the Territory by or on behalf of a Party or its Affiliate.

(d) Samples. With respect to the Product in the U.S., Regeneron shall provide Teva with Product samples for use in the U.S. as and to the extent provided in the U.S. Commercialization Plan. Both Parties (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable approved U.S. Commercialization Plan and shall store and distribute samples in compliance with applicable Laws and Regeneron specifications. Each Party (and its local Affiliates) will maintain those records required by all applicable Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the Product samples on request.

(e) Request for Expanded Promotional Activities in the U.S. In the event that Teva desires to expand the U.S. Commercialization Plan or the corresponding U.S. Commercialization Budget with respect to a Party's and its Affiliates' activities thereunder from the activities and budgeted amounts proposed by Regeneron, then Teva shall propose such expansion to the JCC for consideration in good faith. In the event that the increase is presented by the JCC to the JSC and the JSC does not approve such increase by consensus thereby resulting in an Unresolved Matter, then prior to the Executive Officers meeting to resolve such Unresolved Matter and in any event prior to [**********].

(f) Request for Expanded Promotional Activities in the Ex-U.S. Territory. In the event that Regeneron desires to expand the Ex-U.S. Territory Commercialization Plan or the corresponding Ex-U.S. Territory Commercialization Budget with respect to Teva's and its Affiliates' or its or their Distributor/Commercial Partners' activities thereunder from the activities and budgeted amounts proposed by Teva, then Regeneron shall propose such expansion to the JCC for consideration in good faith. In the event that the increase is presented by the JCC to the JSC and the JSC does not approve such increase by consensus thereby resulting in an Unresolved Matter,

then prior to the Executive Officers meeting to resolve such Unresolved Matter and in any event prior to [**********].

6.5 Product Pricing and Pricing Approvals in the Territory. Regeneron shall determine and establish the price and terms of sale (including any contracting, rebates or discounts) of the Product in the Field for the United States and Teva shall determine and establish the price and terms of sale (including any contracting, rebates or discounts) of the Product in the Field for countries in the Ex-U.S. Territory; *provided that* all such pricing decisions (including rebates or discounts) shall be made in a manner (a) intended to optimize the economic value of the Product in the applicable part of the Territory, (b) consistent with the Collaboration Purpose and (c) taking into consideration the applicable Marketing Guidelines and Pricing Guidelines. Regeneron shall have the right to participate in any material meetings with or the preparation of any material submissions for Governmental Authorities and other Third Party payers relating to any Pricing Approvals in the Ex-U.S. Territory and Teva shall have the right to participate in any material meetings with or the preparation of any material submissions for Governmental Authorities and other Third Party payers relating to any Pricing Approvals in the United States.

6.6 Sales and Product Distribution in the Territory; Other Responsibilities.

(a) Regeneron (or its Affiliate) shall invoice, book, and record all sales of the Product in the U.S. and be responsible for (i) the distribution of the Product in the U.S. and for paying all governmental rebates that are due and owing with respect to the Product in the U.S. (which, for clarity, shall be a deduction from Net Sales), (ii) handling all returns of the Product sold under this Agreement in the U.S. and (iii) handling all aspects of ordering, processing, invoicing, collection, distribution, receivables, reimbursement and patient support programs with respect to the Product in the U.S. Teva (or its Affiliate) shall invoice, book, and record all sales of the Product in each country in the Ex-U.S. Territory and be responsible for (A) the distribution of the Product in such countries and for paying all governmental rebates that are due and owing with respect to the Product in such countries, (B) handling all returns of the Product sold under this Agreement in such countries and (C) handling all aspects of ordering, processing, invoicing, collection, distribution, receivables, reimbursement and patient support programs with respect to the Product in such countries.

(b) Each Party shall maintain records relating to their respective FTEs for the Product in the Field in the United States in a manner sufficient to permit the determination of Field Force Costs and the incentive compensation requirements set forth in the applicable Marketing Guidelines.

6.7 Contract Sales Force. Each Party shall be entitled to engage a Contract Sales Force for up to [**********] of such Party's sales force utilized for the Product to discharge its annual FTE effort with respect to Commercialization of the Product in the United States and Teva shall be entitled to engage a Contract Sales Force for up to [**********] of its sales force utilized for the Product to discharge its annual FTE effort with respect to Commercialization of the Product in the Ex-U.S. Territory taken as a whole; *provided that* in no event shall Teva's Contract Sales Force in any Major Market Country constitute more than [**********] of its sales force utilized for the Product to discharge its annual FTE effort with respect to Commercialization of the Product in such Major Market Country. In the event that Teva or Regeneron does not, or is not reasonably expected to, allocate the number of FTE's required to satisfy at least [**********] of its Co-Promote Commitment Level with respect to the Product in the U.S. under the applicable U.S. Commercialization Plan for a period of at least [**********] (a "Co-Promote FTE Shortfall"), the other Party shall be entitled to conduct such promotion using its own Field Force Personnel or a Contract Sales Force, and in connection therewith, increase its Contract Sales Force on a one-for-one and Target Healthcare Prescriber practice area basis for the number of FTEs that constitute such Co-Promote FTE Shortfall (each, an "Additional CSF Member") to the extent needed (as reasonably determined by the JCC) to account for such shortfall with respect to such Target Healthcare Prescriber practice area. If a Party (or its local Affiliate) retains a Contract Sales Force, that Party (or its local Affiliate) will be responsible for (i) all costs and expenses associated with retaining such Contract Sales Force above approved Field Force Costs included in the applicable U.S. Commercialization Budget or Country/Region Commercialization Budget for its sales force (except with respect to those Additional CSF Members within such Contract Sales Force that are maintained by a Party with respect to the Product in the U.S. because the other Party fails to satisfy its commitment levels in the U.S. as set forth in and in accordance with the second sentence of this Section 6.7, in which event such costs and expenses with respect to such Additional CSF Members shall be borne [**********] by the Party that did not satisfy its Co-Promote Commitment Level (the "Shortfall Party") and shall not constitute Shared Commercial Expenses), (ii) the Contract Sales Force's compliance with this Agreement, including the training and monitoring of such Contract Sales Force and ensuring compliance with all applicable Laws, and (iii) ensuring that sales representatives in such Contract Sales Force have appropriate skill levels customary for sales representatives in major pharmaceutical companies in such country in the relevant therapeutic area. If a Party elects to cover the Shortfall Party's promotional shortfall in accordance with this Section 6.7, (x) the Shortfall Party shall cooperate and coordinate with such Party to enable such Party to perform the promotional shortfall and the Parties will coordinate activities to avoid redundant efforts, and (y) such Party shall be responsible under clauses (ii) and (iii) above applied *mutatis mutandis* with respect to such Additional CSF Members, including that such Additional CSF Members utilize appropriate Promotional Materials consistent with Section 6.8.

6.8 Promotional Materials.

(a) Except as provided in and subject to Section 6.8(b), (i) Regeneron, with respect to the Product in the U.S., will be responsible, consistent with the U.S. Marketing Guidelines and the U.S. Commercialization Plan, and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b), and (ii) Teva, with respect to the Product in the Ex-U.S. Territory, will be responsible, consistent with the Ex-U.S. Territory Marketing Guidelines, and the applicable Ex-U.S. Territory Commercialization Plan, and Country/Region Commercialization Plan, and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b), in each case (i) and (ii), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the U.S. or the Ex-U.S. Territory, as applicable. Each Party will have the right to review and comment on all Promotional Materials for use in any country in the Territory prior to their distribution by the other Party for use in the Territory.

(b) The Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the Product which, in each case, are approved by the JCC or the applicable Country/Region Commercialization Committee if so delegated by the JCC for the applicable Major Market Country. Notwithstanding the foregoing, neither Party shall be required to use any proposed Promotional Materials in a country (or have its name included in any Promotional Materials in a country) that it reasonably determines would violate applicable Laws in such country provided that it so notifies the other Party promptly upon its first receipt of such proposed Promotional Materials.

(c) With respect to Promotional Materials generated for the U.S. for Co-Promotion of the Product by the Parties:

(i) Regeneron shall ensure that Teva's appropriate Field Force Personnel are provided with reasonable quantities of Promotional Materials for the Product for use in the U.S. consistent with Teva's Co-Promote Commitment Level in accordance with the approved U.S. Commercialization Plan.

(ii) Teva shall not change the Promotional Materials in any way, including by: (A) underlining or otherwise highlighting any text or graphics; (B) adding any notes thereto; or (C) using any electronic materials (*e.g.*, PDFs) on any electronic devices other than the specific electronic devices on which, and in the specific format as, Regeneron indicates such electronic material are intended for use.

(iii) All Promotional Materials shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved as set forth in this Agreement.

(iv) Teva shall promptly cease the use of any Promotional Materials when instructed by Regeneron in writing to do so, including in connection with Regeneron's determination, or upon Regeneron's receipt of notice from the FDA's Office of Prescription Drug Promotion (or any successor division having substantially the same functions) that it has made a final determination that any Promotional Materials are not in compliance with applicable Laws.

(d) The Lead Commercialization Party in a country in the Territory shall own all rights to all Promotional Materials with respect to the Product in such country, including all copyrights thereto.

(e) Upon expiration of this Agreement, at Regeneron's election, Teva either shall (i) return to Regeneron or (ii) destroy and certify to Regeneron such destruction, all Promotional Materials not distributed to Healthcare Prescribers and in the possession of, or under the control of, Teva.

6.9 Promotional Claims/Compliance. Neither a Party nor any of its Affiliates or Distributor/Commercial Partners shall make any medical or promotional claims for the Product in the Field in the Territory other than as permitted by applicable Laws. When distributing information related to the Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates (and Distributor/Commercial Partners) shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country, including the American Medical Association Guidelines on Gifts to Physicians from Industry and the PhRMA Code on Interactions with Healthcare Professions, if applicable.

6.10 Restriction on Bundling in the Territory. If a Party or its Affiliates or Distributor/Commercial Partners sell the Product in the Field in the Territory under this Agreement to a customer who also purchases other products or services from any such entity, such Party agrees not to, and to require its Affiliates and Distributor/Commercial Partners not to, (a) discount or price the Product in a manner that (i) is reasonably likely to disadvantage the Product in order to benefit sales or prices of other products offered for sale by such Party or its Affiliates or Distributor/Commercial Partners to such customer, (ii) is inconsistent with the Collaboration Purpose or (iii) would result in pricing and discounting inconsistent with the applicable Pricing Guidelines or (b) bundle or include the Product as part of any multiple product offering.

6.11 Inventory Management. The Lead Commercialization Party in a country or region in the Territory shall use Commercially Reasonable Efforts to manage inventory of the Product on hand at such Party, its Affiliates and wholesalers and distributors (including Distributor/Commercial Partners) in such country or region so as to maintain levels of inventory appropriate

for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.12 Medical and Consumer Inquiries. The JCC shall establish guidelines to handle medical questions or inquiries from consumers relative to the Product in the Field in the Territory. Without limitation of the foregoing, [**********].

6.13 Post Marketing Clinical Trials. Subject to the provisions of this Agreement, the Parties shall comply with any clinical trial, registry, observation study or other similar obligation with respect to a Marketing Approval with respect to the Product for use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority, which clinical trial shall be included in the Global Development Plan or the Ex-U.S. Territory Development Plan, as applicable, and the costs expenses associated with such obligations shall be Global Development Costs or Ex-U.S. Territory Development Costs, as applicable.

6.14 Territorial Restrictions.

(a) Teva, except to the extent prohibited by applicable Law, (i) shall, and shall cause its Affiliates and its and their Distributor/Commercial Partners to, distribute, offer for sale and sell the Product only in the Ex-U.S. Territory and (ii) shall not, and shall not permit its Affiliates and its and their Distributor/Commercial Partners to, distribute, offer for sale or sell the Product (A) to any Person outside of the Ex-U.S. Territory or (B) to any Person inside the Ex-U.S. Territory that (x) is reasonably likely to directly or indirectly distribute, offer for sale or sell the Product outside of the Ex-U.S. Territory or assist another Person to do so or (y) has directly or indirectly distributed, offered for sale or sold the Product outside the Ex-U.S. Territory or assisted another Person to do so. If Teva, or any of its Affiliates or its or their Distributor/Commercial Partners receives any orders for the Product outside of the Ex-U.S. Territory, subject to applicable Law, such Person shall refer such orders to Regeneron.

(b) Regeneron, except to the extent prohibited by applicable Law, (i) shall, and shall cause its Affiliates and its and their Distributor/Commercial Partners to, distribute, offer for sale or sell the Product only outside of the Ex-U.S. Territory, and (ii) shall not, and shall not permit its Affiliates to, distribute, offer for sale or sell the Product (A) to any Person in the Ex-U.S. Territory or (B) to any Person in the U.S. that (x) is reasonably likely to directly or indirectly distribute, offer for sale or sell the Product in the Ex-U.S. Territory or assist another Person to do so or (y) has directly or indirectly distributed, offered for sale or sold the Product inside the Ex-U.S. Territory or assisted another Person to do so. If Regeneron, or any of its Affiliates or its or their Distributor/Commercial Partners receives any orders for the Product in the Ex-U.S. Territory, subject to applicable Law, such Person shall refer such orders to Teva. Nothing in this Section 6.14(b) shall limit Regeneron from supplying the Product to Teva pursuant to this Agreement and the

Ancillary Agreements or, solely with respect to the Excluded Territory, to any Person under the Mitsubishi Agreement.

ARTICLE VII
CLINICAL AND REGULATORY AFFAIRS

7.1 Ownership of Approvals and Registration Filings. Unless otherwise agreed to by the Parties, subject to Section 7.9:

(a) Regeneron shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings with respect to (i) the Development of the Product in the Field in the Territory other than with respect to Development under the Ex-U.S. Territory Development Plan [**********], (ii) the Commercialization of the Product in the Field in the United States, and [**********] and (ii) prepare and file all Registration Filings with respect to, and hold, the Marketing Approvals for the Product in the United States.

(b) Subject to Section 7.7 and Section 8.7, Teva shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings with respect to (i) the Development of the Product in the Field in the Ex-U.S. Territory under the Ex-U.S. Territory Development Plan, [**********], the Commercialization of the Product in the Field in the Ex-U.S. Territory, [**********]. For clarity, except as otherwise provided in this Agreement, Teva shall have the right to [**********].

(c) Subject to Section 7.7, the Lead Regulatory Party shall, as reasonably necessary to permit the other Party to perform its obligations or exercise its rights under this Agreement, license, transfer, provide a letter of reference with respect to, or take such other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

(d) Subject to Section 7.7, the non-Lead Regulatory Party shall provide such assistance with respect to regulatory matters as is reasonably requested by the Lead Regulatory Party and consistent with the terms of this Agreement, the cost and expense of such assistance to be [**********] with respect to regulatory matters in the U.S. and shall be borne solely by the Lead Regulatory Party with respect to such regulatory matters in the Ex-U.S. Territory.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate applicable regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the

matters for which it is the Lead Regulatory Party; *provided that* it shall adhere to the obligations in this ARTICLE VII. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and any Additional Trial Plans, and all applicable Laws.

(b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development or Commercialization of the Product in the Field in the Territory, including, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities and (ii) to comply with applicable Laws in connection with the Development or Commercialization of the Product in the Field anywhere in the Territory. The Parties shall provide to each other prompt written notice of any Approval of the Product in the Field anywhere in the Territory. Except with respect to [**********], strategies and with respect to all material regulatory actions, communications and regulatory filings for the Product in the Field in the Territory.

(c) [**********], the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities pertaining to the Development or Commercialization of the Product in the Field in the Territory under the Plans or any Additional Trial Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including, all annual and periodic safety reports for the Product in the Field), and consistent with applicable Laws, to have up to [**********] representatives from the other Party attend and actively participate in all material, pre-scheduled meetings, telephone conferences or discussions with Regulatory Authorities to the extent such material meetings, telephone conferences or discussions pertain to the Development or Commercialization of the Product in the Field in the Territory. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis (or at such times as determined by the JDC) with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

(d) Without limiting the foregoing, any Registration Filing that deviates from the Company Core Data Sheet or that includes changes from the Common Technical Document must be approved by the JDC prior to submission to the applicable Regulatory Authority.

7.3 Regulatory Events. Each Party shall keep the other Party informed, as early as practicable and in no event after [**********] after notification (or other time period specified below), of any action by, or notification or other information that it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, that:

(a) raises any material concerns regarding the safety or efficacy of the Product in the Field;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Product in the Field under the Plans or any Additional Trial Plan; *provided that* each Party shall inform the other Party of the foregoing no later than [**********] after receipt of a notification referred to in this clause (b); or

(c) is reasonably likely to lead to a recall or market withdrawal of the Product in the Field anywhere in the Territory.

Information that shall be disclosed pursuant to this Section 7.3 shall include, but not be limited to the following matters with respect to the Product in the Territory:

(i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the extent involving matters described in clauses (a), (b) or (c) of this Section 7.3;

(iii) receipt of a warning letter issued by a Regulatory Authority;

(iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and

(v) receipt of product complaints concerning actual or suspected Product tampering, contamination, or mix-up (e.g., wrong ingredients).

7.4 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall, in accordance with the Safety Data Exchange Agreement, be responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies with respect to the matters for which it is the Lead Regulatory Party, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning pharmacovigilance and risk management plans and product complaint reporting in all countries in the Territory in which the Product is being Developed, Manufactured, or Commercialized. Without limitation to the foregoing, the Parties shall negotiate in good faith and execute a safety data exchange agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse events/adverse drug reactions and Product complaints to ensure timely communication to Regulatory Authorities and compliance with applicable Laws (the "Safety Data Exchange Agreement"), and will use good faith efforts to execute such Safety Data Exchange Agreement within [**********] after the Effective Date. The Parties shall update the Safety Data Exchange Agreement prior to the First Commercial Sale in the Territory. Regeneron shall be responsible for the establishment, holding and maintenance of the global safety database with respect to the Product and establishing the direction for global safety and risk management strategies for the Product; *provided that* Regeneron shall meaningfully consult in good faith with Teva regarding the foregoing. The costs and expenses with respect to such global safety database shall be [**********].

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7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to the Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development or Commercialization [**********] of the Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority, the receiving Party will promptly provide a copy to the other Party [**********], and the Party in receipt of the observations will prepare any appropriate responses; [**********]. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response.

7.6 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to the Product in the Field in the Territory shall be made only upon [**********], which agreement shall not be unreasonably withheld, conditioned or delayed; *provided that* nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or applicable Law. The Party that determines that a recall or market withdrawal of the Product in the Field in the Territory may be required shall, within [**********], notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Costs and expenses associated with such recalls in the U.S. will be [**********].

7.7 Manufacturing Information. [**********].

7.8 Rights of References.

(a) Subject to the terms and conditions of this Agreement and any License to which Regeneron or any of its Affiliates is a party, Regeneron hereby grants to Teva, solely with respect to the Product under this Agreement, a co-exclusive right of reference, with the right to grant further rights of reference to any Distributor/Commercial Partner without requirement for Regeneron's consent or to any subcontractor (subject to Regeneron's consent not to be unreasonably withheld, conditioned or delayed), under any Registration Filings or Approvals Controlled by Regeneron or any of its Affiliates or Distributor/Commercial Partners as and to the extent relating to the Product as necessary or reasonably useful to Develop the Product in the Field in the Territory under the Ex-U.S. Territory Development Plan or any Teva Additional Trial Plan or to Commercialize the Product in the Field solely in the Ex-U.S. Territory pursuant to the Ex-U.S. Territory Commercialization Plan; [**********].

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(b) Subject to the terms and conditions of this Agreement and any License to which Teva or any of its Affiliates is a party, Teva hereby grants to Regeneron (i) a co-exclusive right of reference, with the right to grant further rights of reference to any Person, under any Registration Filings or Approvals Controlled by Teva or any of its Affiliates as and to the extent relating to the Product as necessary or reasonably useful to Develop the Product in the Field in the Territory under the Global Development Plan or any Regeneron Additional Trial Plan or Commercialize the Product in the Field solely in the United States pursuant to the U.S. Commercialization Plan and (ii) an exclusive (including with respect to Teva and its Affiliates) right of reference, with the right to grant further rights of reference to any Person, under any Registration Filings or Approvals Controlled by Teva or any of its Affiliates to the extent relating to the Product

as necessary or reasonably useful to Manufacture the Product worldwide or to Develop or commercialize or otherwise exploit the Product outside the Territory.

7.9 Regulatory Filings for Marketing Approvals. Regeneron shall prepare, with meaningful participation and input from Teva (except with respect to Manufacturing), the Common Technical Document and the Company Core Data Sheet for the Product in the Territory (the cost and expense of which shall be Global Development Costs); *provided that* Teva shall prepare with meaningful participation and input from Regeneron, any changes to the Common Technical Document or the Company Core Data Sheet solely for the Ex-U.S. Territory that result from Development conducted under the Ex-U.S. Territory Development Plan or any Teva Additional Trial Plan (the cost and expense of which shall be Ex-U.S. Territory Development Costs). The Common Technical Document, the Company Core Data Sheet and any changes to these documents shall be submitted to the JDC and the JSC for review and approval as provided for in this Agreement. When seeking Marketing Approval in a country in the Territory, the Lead Regulatory Party for a country in the Territory shall use the Common Technical Document, with any changes or supplements as may be required for Registration Filings for Marketing Approval under applicable Law, or by the applicable Regulatory Authorities, in such country and shall not agree to (a) any changes to the Common Technical Document or (b) product labeling that deviates from the Company Core Data Sheet, without the approval of the JSC. Disputes with respect to deviations from the Common Technical Document or the Company Core Data Sheet that are required by applicable Law or the applicable Regulatory Authorities in a country shall be a Legal Dispute. All other disputes with respect to deviations from the Common Technical Document or the Company Core Data Sheet shall be resolved by [**********].

ARTICLE VIII
MANUFACTURING AND SUPPLY

8.1 Regeneron Supply of Product. Regeneron shall have the exclusive right and responsibility to Manufacture or have Manufactured and supply or have supplied the Product for all Development and Commercialization purposes in the Field in the Territory. As of the Effective Date, Regeneron or one of its Affiliates (a) Manufactures the Formulated Bulk Product in its own facilities and (b) uses a Third Party to perform the finishing, filling, device manufacture and assembly, packaging and testing of the Finished Product. In its discretion, subject to this Section 8.1, Regeneron may [**********].

8.2 Global Territory Development. Regeneron [**********] Manufacture (or have Manufactured) and supply (or have supplied) all Product and placebo necessary to conduct

Development in accordance with the Global Development Plan. For clarity, the Development Supply Costs with respect to the Product shall be included in the Global Development Costs that shall be shared by the Parties in accordance with Section 9.2(a).

8.3 Development Supply Agreement. Within [**********] following the Effective Date (or such other timeframe as may be mutually agreed by the Parties), the Parties shall negotiate and execute a definitive supply agreement ("Development Supply Agreement") for the supply of Teva's Development Supply Requirements solely for use in conducting Ex-U.S. Territory Development under the Ex-U.S. Territory Development Plan and Development for an [**********] in the Territory under any [**********], accordingly. The Development Supply Agreement shall provide for customary terms and conditions, including forecasting, ordering, delivery, payment and supply, consistent with the terms set forth in Schedule 8.3 and the terms of this Agreement. Regeneron may designate an Affiliate to enter into the Development Supply Agreement. The price for Development Supply Requirements supplied by Regeneron to Teva under the Development Supply Agreement shall be the Development Supply Cost therefor, [**********].

8.4 U.S. Commercial Supply. Regeneron shall [**********] to Manufacture (or have Manufactured) and supply (or have supplied) the Commercial Supply Requirements for U.S. Commercialization in accordance with the approved U.S. Commercialization Plan. For clarity, the COGS for the Product included in the Commercial Supply Requirements for U.S. Commercialization shall be taken into account in determining U.S. Gross Profits, excluding any Product for which the Commercial Supply Cost is included in Development Costs.

8.5 Ex-U.S. Territory Commercial Supply Agreement. At least [**********] prior to the date the first Marketing Approval in the Ex-U.S. Territory is anticipated to be obtained by Teva, the Parties shall negotiate and execute a definitive commercial supply agreement ("Commercial Supply Agreement") for the supply of Teva's Commercial Supply Requirements to Teva solely for Commercialization in the Ex-U.S. Territory in accordance with the approved Ex-U.S. Territory Commercialization Plan. The Commercial Supply Agreement shall provide for customary terms, including forecasting, ordering, delivery, payment and supply, consistent with the terms of this Agreement. Regeneron may designate an Affiliate to enter into the Commercial Supply Agreement. Except as otherwise mutually agreed by the Parties and set forth in the Commercial Supply Agreement, the Product supplied under the Commercial Supply Agreement shall be in filled, packaged and labeled form. The price for the Product supplied by Regeneron to Teva under the Commercial Supply Agreement shall be the Purchase Price as provided in Section 9.6, [**********].

8.6 Quality Agreements. Within [**********] following the Effective Date (or such other timeframe as may be mutually agreed by the Parties), but in any event prior to [**********], the Parties shall negotiate and execute a reasonable and customary quality agreement with respect to the Product to be Manufactured by or for Regeneron and supplied to Teva under the Development Supply Agreement (the "Development Quality Agreement"). At least [**********] prior to the expected date the first Marketing Approval in the Ex-U.S. Territory is anticipated to be obtained by Teva, the Parties shall negotiate and execute a reasonable and customary quality agreement with respect to the Product to be Manufactured by or for Regeneron and supplied to Teva under the Commercial Supply Agreement (the "Commercial Quality Agreement").

8.7 Manufacturing Process Improvements. Notwithstanding anything to the contrary in this Agreement, the Commercial Supply Agreement, the Development Supply Agreement or either Quality Agreement, Regeneron shall have the right, in its discretion, to make improvements to or otherwise modify the Manufacture of the Product from time to time ("Manufacturing Process Improvements") in accordance with the Global Development Plan; [**********].

8.8 Manufacturing Shortfall.

(a) [**********].

(b) Regeneron shall provide prompt written notice to Teva if (i) it reasonably determines that it will not be able to supply the Product in accordance with the Global Development Plan, U.S. Commercialization Plan, Development Supply Agreement, Commercial Supply Agreement, or Additional Trial Plan or (ii) it becomes aware of any problems or delays of any nature in performing its contractual obligations that have the potential to adversely affect the Manufacturing of the Product, as the case may be, and in each of (i) and (ii) along with the reason for such inability or delay and of the expected duration thereof, as the case may be, and will keep Teva informed on a timely basis of any developments during any such period of time. Upon such notification, subject to and without limiting any applicable terms and conditions regarding supply failure in the Development Supply Agreement and the Commercial Supply Agreement, the matter will be referred to the JSC to determine whether an alternative Third Party supply source of the Product should be utilized; [**********].

(c) Unless otherwise agreed by the Parties, the JSC shall allocate Regeneron's capacity for the Manufacture of Finished Product for the Territory in accordance with the Collaboration Purpose in descending order of priority, as follows: [**********]. Any dispute regarding any such allocation shall be treated as a "Legal Dispute" hereunder.

8.9 Safety Stock.

(a) Ex-U.S. Territory. Regeneron shall [**********] maintain, [**********] safety stock [**********].

(b) United States. Regeneron shall [**********] maintain [**********] safety stock [**********].

8.10 Ex-U.S. Territory Product Changes. Subject to Teva's payment obligations under Section 9.7, Regeneron shall [**********] to perform (or have performed) any Ex-U.S. Territory Product Changes approved by the JSC.

8.11 Manufacturing Compliance. Regeneron shall [**********] Manufacture the supplied Product under this ARTICLE VIII or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices, the Quality Agreement and applicable Laws.

8.12 Comparator Supply. If any comparator agent required for activities contemplated under a Development Plan is a product that a Party or any of its Affiliates manufactures, has manufactured or otherwise distributes, such Party shall [**********] provide such comparator agent for use under such Development Plan at such Party's (or its Affiliate's) cost and pursuant to reasonable and customary supply terms and conditions agreed to by the Parties.

ARTICLE IX
PERIODIC REPORTS; PAYMENTS

9.1 Upfront Payment. Within [**********] after the Effective Date, Teva shall pay to Regeneron a non-refundable, non-creditable amount of two hundred and fifty million Dollars ($250,000,000) as compensation for Regeneron's share of Global Development Costs and costs and expenses incurred by Regeneron as of the Effective Date with respect to Manufacturing activities for the Product.

9.2 Development Costs.

(a) Global Development. Except as set forth in Section 5.3(a), the Parties shall share equally (50%/50%) in (i) the total Development Costs for the Product under the Global Development Plan (including the preparation of the Common Technical Document and the Company Core Data Sheet and any change to either of the foregoing) and (ii) any other amounts that are

specified as "Global Development Costs" under this Agreement, in each case ((i) and (ii)), [**********] and whether incurred by or on behalf of Teva, Regeneron or their respective Affiliates (the "Global Development Costs"), and such Global Development Costs shall be counted toward the Global Development Cost True-Up as set forth in Schedule 3. For clarity, no such Global Development Costs incurred by either Party or its respective Affiliates shall be shared as Other Shared Expenses.

(b) Ex-U.S. Territory Development. Teva shall be responsible for paying [**********] of (i) the total Development Costs for the Product under the Ex-U.S. Territory Development Plan (or the Global Development Plan pursuant to Section 5.3(a)) and (ii) any other amounts that are specified as "Ex-U.S. Territory Development Costs" under this Agreement, in each case ((i) and (ii)), [**********] whether incurred by or on behalf of Teva, Regeneron or their respective Affiliates (the "Ex-U.S. Territory Development Costs"). Any Ex-U.S. Territory Development Costs incurred by or on behalf of Regeneron shall be reimbursed by Teva [**********]. For clarity, no Ex-U.S. Territory Development Costs incurred by either Party shall be shared as Other Shared Expenses.

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(c) Additional Trial Costs. With respect to a given Additional Trial conducted hereunder for [**********] that is not a Set Indication or a Selected Combination Therapy, Additional Trial Costs shall be shared as provided in this Section 9.2(c). Except as expressly provided in this Section 9.2(c) or as may otherwise be agreed to by the Parties in writing, [**********].

(i) [**********].

(ii) [**********].

(iii) [**********].

(iv) [**********].

(v) For clarity, [**********].

9.3 Development Milestone Payments.

(a) Subject to this Section 9.3, Teva shall make a one-time (except as provided below in clause (b)(ii)), non-refundable, non-creditable milestone payment to Regeneron within [**********] after the first achievement of each of the following milestone events for the Product (each, a "Development Milestone Event" and the corresponding payment, a "Development

Milestone Payment") to support Regeneron's share of Global Development Costs and Regeneron's Manufacturing activities:

Development Milestone Event	Development Milestone Payment ($)
(A) First dosing of the first patient in the [**********] of the Product to assess efficacy under [**********] for the Indication of [**********]	$[**********]
(B) First dosing of the first patient in the [**********] of the Product under [**********] for [**********]	$[**********]
(C) [**********] for the [**********] of the Product under [**********] for the Indication of [**********]	$[**********]
(D) [**********] for the [**********] of the Product under [**********] for [**********]	$[**********]
(E) Receipt of the [**********] of the Product in [**********]for the Indication of [**********]	$[**********]
(F) Receipt of the [**********] of the Product in [**********] for [**********]	$[**********]
(G) Receipt of the [**********]of the Product for the Indication of [**********] in [**********]	$[**********]
(H) Receipt of the [**********] of the Product for [**********] in [**********]	$[**********]

If any given Development Milestone Payment is due and one or more previous Development Milestone Payments for Development Milestone Events that would reasonably have been anticipated to precede such Development Milestone Payment have not been paid for any reason, then payment of all such preceding unpaid Development Milestone Payments will be due at such time as well. For example, if [**********].

The milestone events above reference either of two conditions, the Indication of [**********]. The Parties acknowledge that the milestone events referencing these conditions may occur separately; may occur together as part of the same [**********] or commercially sold Product; or may occur together or separately within another Indication or within an Indication that is specific to [**********].

(b) [**********]:

(i) [**********]

(ii) [**********]:

(1) [**********].

(2) [**********].

9.4 U.S. Net Sales Milestones. Teva shall pay to Regeneron the following one-time, non-refundable, non-creditable sales milestone payments within [**********] from receipt of invoice following the end of the Quarter within the [**********] in which the sales amounts described in the table below is first achieved:

Sales Amounts	**Payment**
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the United States	$[**********]

For purposes of the foregoing table, references to "annual Net Sales" shall mean Net Sales in any [**********].

9.5 U.S. Gross Profit Split: Shared Commercial Expenses; Other Shared Expenses; Ex-U.S. Territory Global Commercialization Costs.

(a) Commencing on the Effective Date and continuing during the Term, the Parties shall share the U.S. Gross Profit Split, the Shared Commercial Expenses and Other Shared Expenses, each as described in Schedule 3.

(b) Teva shall be responsible for paying [**********] of the Ex-U.S. Territory Global Commercialization Costs. [**********] through the [**********] as set forth in Schedule 3.

9.6 Ex-U.S. Territory Purchase Price. The purchase price for the Product supplied under the Commercial Supply Agreement ("Purchase Price") shall be paid in the manner and in the amount set forth in this Section 9.6:

(a) Teva shall pay the Commercial Supply Cost of the Product, by multiplying (i) the number of units of Product delivered by Regeneron, by (ii) the Commercial Supply Cost per unit, calculated in accordance with Section 9.6(g) ("Initial Purchase Price") within [**********].

(b) With respect to each Quarter after the First Commercial Sale in the Ex-U.S. Territory, Teva shall pay to Regeneron the following payment adjustment ("Purchase Price Adjustment A") for Product supplied under the Commercial Supply Agreement, [**********]:

Annual Net Sales in the Ex-U.S. Territory	**Purchase Price Adjustment A (% of Net Sales)**
On the portion of aggregate annual Net Sales of the Product in the Ex-U.S. Territory up to and including $[**********] in a given Calendar Year	[**********]%
On the portion of aggregate annual Net Sales of the Product in the Ex-U.S. Territory over $[**********] and up to and including $[**********] in such Calendar Year	[**********]%
On the portion of annual Net Sales of the Product in the Ex-U.S. Territory over $[**********] and up to and including $[**********] in such Calendar Year	[**********]%
On the portion of annual Net Sales of the Product in the Ex-U.S. Territory over $[**********] and up to and including $[**********] in such Calendar Year	[**********]%
On the portion of annual Net Sales of the Product in the Ex-U.S. Territory over $[**********] in such Calendar Year	[**********]%

(c) Third, Teva shall pay to Regeneron the following one-time, non-refundable, non-creditable payments ("Purchase Price Adjustment B," together with any Purchase Price Adjustment A, the "Purchase Price Adjustments") through the Quarterly True-Up as set forth in Schedule 3 after the end of the Quarter in which the sales amounts described in the table below is first achieved:

Aggregate Annual Net Sales Amounts	Purchase Price Adjustment B Payment
First achievement of $[**********] of aggregate annual Net Sales of the Product in the Ex-U.S. Territory	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the Ex-U.S. Territory	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the Ex-U.S. Territory	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the Ex-U.S. Territory	$[**********]
First achievement of $[**********] of aggregate annual Net Sales of the Product in the Ex-U.S. Territory	$[**********]

For purposes of the foregoing table, references to "annual Net Sales" shall mean Net Sales in any [**********]. Each Purchase Price Adjustment B shall only be payable once, regardless of the number of times the sales amounts described in the table above is achieved by the Product in subsequent Quarters.

(d) [**********].

(e) [**********].

(f) [**********].

(g) [**********].

(h) [**********].

9.7 Ex-U.S. Territory Product Changes. Any Development Costs incurred by Regeneron for the Manufacture of the Product that result from any Ex-U.S. Territory Product Change pursuant to Section 8.10 shall constitute [**********].

9.8 Budget Overruns.

(a) Neither Party shall be required to pay its share of any Development Costs for a Calendar Year with respect to activities to be performed by the other Party under a Development Plan that are in excess of [**********] of the total amounts that are in the applicable Development Budget for activities to be performed by such other Party for such Calendar Year

("Development Overrun"), unless such Development Overrun [**********] (each, a "Permitted Development Overrun"). Otherwise, the Party responsible for the Development activities that caused the overrun [**********].

(b) Neither Party shall be required to pay any Shared Commercial Expenses with respect to activities performed by the other Party pursuant to the U.S. Commercialization Plan that are in excess of [**********] of the total amounts that are in the U.S. Commercialization Budget for activities to be performed by such other Party for such Calendar Year ("Commercialization Overrun") unless such Commercialization Overrun[**********] (each, a "Permitted Commercialization Overrun"). Each Commercialization Overrun [**********].

(c) In the event that, during any Calendar Year, any Development Cost or Shared Commercial Expenses expressly provided for in the applicable Development Budget or U.S. Commercialization Budget, as applicable, to be incurred during such Calendar Year are not incurred during such Calendar Year, then such budgeted[**********].

(d) In the event that, during any Calendar Year, any Development Cost incurred during such Calendar Year in excess of the amount expressly provided for in the applicable Development Budget were anticipated to be incurred in the following Calendar Year based on the then-current non-binding [**********] budget forecast in the applicable Development Plan, then [**********].

(e) Any Development Overruns or Commercialization Overruns that, pursuant to Section 9.8(a) or Section 9.8(b), as applicable, a Party is not required to pay shall not be included in the calculation of the Quarterly True-Up. [**********].

9.9 Periodic Reports. Teva and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.3(e).

(b) Within [**********] after the end of each month, (i) commencing with the month in which the First Commercial Sale in the United States occurs, Regeneron shall deliver electronically to Teva a monthly estimate of detailed Net Sales report with monthly and year-to-date estimated sales for the Product in the United States in Dollars and (ii) commencing with the month in which the First Commercial Sale in the Ex-U.S. Territory occurs, Teva shall deliver electronically to Regeneron a monthly estimate of detailed Net Sales report with monthly and year-to-date estimated sales for the Product in the Ex-U.S. Territory (on a country-by-country basis) in Dollars.

(c) Within [**********] after the end of each Quarter, commencing with the Quarter in which First Commercial Sale in the United States occurs, Regeneron shall deliver electronically to Teva a written report setting forth for such Quarter (i) the Net Sales of the Product in the United States, (ii) Product quantities sold in the United States by dosage form and unit size, (iii) gross Product sales in the United States and an accounting of the deductions from gross sales permitted by the definition of Net Sales and (iv) the COGS incurred by Regeneron or its Affiliates with respect to Product sold in such Quarter in the United States.

(d) (i) Within [**********] after the end of each Quarter, commencing with the Quarter in which the First Commercial Sale in the Ex-U.S. Territory occurs, Teva shall deliver electronically to Regeneron a written inventory report (the "Quarterly Inventory Report") setting forth [**********]. An example of the Quarterly Inventory Report is set forth on Exhibit A.

(ii) Within [**********] after the end of each Calendar Year, commencing with the Calendar Year in which the First Commercial Sale in the Ex-U.S. Territory occurs, Teva shall deliver electronically to Regeneron a written inventory report (the "Annual Inventory Report") reconciling beginning and ending inventory as set forth on Exhibit A and including [**********]. An example of the Annual Inventory Report is set forth on Exhibit A.

(e) Within[**********] after the end of each Quarter, commencing with the Quarter in which First Commercial Sale in the Ex-U.S. Territory occurs, Teva shall deliver electronically to Regeneron a written report setting forth for such Quarter (i) on a country-by-country basis in the Ex-U.S. Territory for such Quarter (A) the estimated Net Sales of the Product in the Ex-U.S. Territory in local currency and in Dollars, (B) estimated gross Product sales in the Field in the Ex-U.S. Territory and an accounting of the deductions from gross sales permitted by the definition of Net Sales and (C) estimated Product quantities sold in the Ex-U.S. Territory by dosage form and unit size; (ii) the estimated applicable Purchase Price Adjustment A percentage rate(s) under this Agreement for Product sold in the Ex-U.S. Territory during such Quarter, calculated as set forth above; (iii) the estimated Purchase Price Adjustments (including any Purchase Price Adjustment B) payable in the country's currency where such Net Sales occurred; (iv) the applicable exchange rate to convert from each country's currency to United States dollars under Section 9.13; and (v) the estimated net Purchase Price Adjustment payable in Dollars. An example of the Purchase Price Adjustment calculation is set forth on Exhibit B. [**********].

(f) Within [**********] following the end of each Quarter, each Party that has incurred any Other Shared Expenses or Shared Commercial Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the estimated Other Shared Expenses or Shared Commercial Expenses incurred by such Party in such Quarter on a country-by-country basis, including whether any such expenses are also included in the reports

delivered pursuant to clause (g) below. Each Party shall deliver electronically to the other Party a final report with respect to the content of this Section 9.9(f) within [**********] days after the end of each Quarter in which such Party has incurred any Other Shared Expenses or Shared Commercial Expenses.

(g) Within [**********] days after the end of each Quarter, (i) commencing with the Quarter in which the First Commercial Sale in the United States occurs (or such earlier agreed upon Quarter, if appropriate), each Party shall provide to the other Party and (ii) commencing with the Quarter in which the First Commercial Sale in a Reporting Country/Region in the Ex-U.S. Territory occurs, with respect to the Product in each Reporting Country/Region in the Ex-U.S. Territory, Teva shall provide to Regeneron, in either case ((i) or (ii)), in electronic form, a report summarizing in reasonable detail the marketing, Detailing (including the Healthcare Prescriber, number of products detailed and the position of the Detail for the Product), selling and promotional activities undertaken by such Party (or its Affiliates), including its Field Force Personnel, during the previous Quarter in such Reporting Country/Region, which report shall include reasonable data from reports created by such Party for its internal management purposes.

(h) With respect to each Quarter, no later than the later of (i) [**********] following the end of such Quarter and (ii) [**********] following Regeneron's receipt of each report Teva is required to deliver to Regeneron pursuant to each of Section 5.3(e), Section 9.9(d), Section 9.9(e) and Section 9.9(f), as applicable, Regeneron shall calculate each True-Up (as defined in Schedule 3) for such Quarter in accordance with Schedule 3 and provide Teva an electronic report showing the calculation of each True-Up (a "Quarterly True-Up Report"). In the event there is any dispute relating to a Quarterly True-Up Report for a Quarter, such matter shall be submitted to the JFC for resolution. In the event that no resolution is reached by the JFC, the matter shall be escalated to the JSC in accordance with Section 3.11(a) and, if necessary, to the Executive Officers in accordance with Section 3.11(c) and [**********].

(i) All reports referred to in this Section 9.9 and Section 5.3(e) shall be in such form and level of detail as may be approved by the JFC. Unless otherwise agreed by the JFC, the financial data in the reports will include calculations in local currency and Dollars.

9.10 Funds Flow. The Parties shall make Quarterly True-Up payments in accordance with the mechanism set forth in Schedule 3. If Teva owes any True-Up payment based on the calculations for such True-Up in the applicable Quarterly True-Up Report for a Quarter, it shall, subject to Section 9.17, make such payment to Regeneron within [**********] after receipt of an invoice from Regeneron for such amount. If Regeneron owes any True-Up payment based on the calculations in the applicable Quarterly True-Up Report for a Quarter, it shall, subject to Section 9.17, make such payment to Teva within [**********] after receipt of an invoice from Teva for such amount.

9.11 Invoices and Documentation. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder. All payments otherwise due and owing under this Agreement shall be supported by, and, if any such payment is due hereunder within a specified time period, such specified time period shall not start running until receipt by the owing Party of, an invoice delivered (whether electronically or physically) to the Party owing such amount, except as provided in Section 9.1, in such form approved by the JFC.

9.12 Budgets and Forecasts. With respect to each Plan delivered hereunder, such Plan shall include a binding budget as part of such Plan and an associated non-binding [**********] budget forecast (i.e., the Global Development Budget, Ex-U.S. Territory Development Budget, Ex-U.S. Territory Commercialization Budget, U.S. Commercialization Budget, or Country/Region Commercialization Budget, as applicable), which shall include a break-out of the expenditures by Quarter for the initial Calendar Year of such annual budget and on an annual basis for the next [**********]. By no later than [**********] of each Calendar Year, each Party will provide the other Party with a good faith estimate of a re-forecast of the projected expenditures, by Quarter, for the remaining portion of the initial Calendar Year for each such budget. Notwithstanding the foregoing, such reforecast shall not in any way alter or amend the budgeting process required under this Agreement, including Section 5.3(d).

9.13 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in Dollars. In those cases where the amount due in Dollars is calculated based upon one or more currencies other than Dollars, such amounts shall be converted to Dollars at the average rate of exchange for the Quarter to which such payment relates using the arithmetic mean of the daily rate of exchange, as reported in *Thomson Reuters Eikon* as the "Mid Price Close", or using any other source as agreed to by the Parties.

9.14 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to one month London Inter-Bank Offering Rate (LIBOR) Dollars, as quoted on Thomson Reuters Eikon (or any other source agreed to by the Parties) effective for the date on which the payment was due, plus [**********] (such sum being referred to as the "Default Interest Rate").

9.15 Taxes.

(a) Any and all payments by or on account of any obligation of a Party under this Agreement shall be made without deduction or withholding for any taxes, except as required by applicable Law. If any applicable Law (as determined in the good faith discretion of an applicable Party) requires the deduction or withholding of any tax from any such payment by a Party, then the applicable Party shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable Law; provided that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable); [**********]. Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.

(b) If either Party assigns this Agreement to an Affiliate or Third Party and, as a result of such assignment, any amounts payable hereunder are subject to additional withholding tax, such assigning Party shall be responsible for the resulting additional withholding taxes such that the applicable payment shall be made to the non-assigning Party without deduction for any such withholding; provided, however, that if the non-assigning Party derives a tax benefit (including through the use of foreign tax credit) that is finally determined and adjudicated on a with and without basis as a result of such additional withholding, then the non-assigning Party shall promptly reimburse the assigning Party for the amount of such benefit; provided, further, that the non-assigning Party shall take all commercially reasonable actions necessary to obtain any tax benefit (including through the use of foreign tax credit) with respect to such additional withholding taxes and to defend such benefit in a tax audit.

9.16 Adjustments to FTE Rates. Upon the request of either Party [**********], the Parties shall meet to review the accuracy of an applicable FTE Rate in any country (e.g., Field Force FTE Rate, the Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE Rate and to determine in good faith whether to adjust the rate(s) in any country. In the event there is any dispute relating to an adjustment to an FTE Rate, such matter shall be submitted to the JFC for resolution. In the event that no resolution is reached by the JFC, the matter shall be escalated to the JSC in accordance with Section 3.11(a) and, if necessary, will be treated as a Financial Dispute and escalated to the Executive Officers in accordance with Section 3.11(c) and [**********].

9.17 Right to Offset Payments. Subject to Section 9.15 and except as otherwise provided in Section 9.3, Section 9.4 or Section 9.6, [**********].

9.18 Resolution of Payment Disputes. In the event there is a dispute relating to any of the payment obligations or reports under this ARTICLE IX, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than [**********] after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be escalated to the JSC in accordance with Section 3.11(a) and, if necessary, to the Executive Officers in accordance with Section 3.11(b) and [**********]. Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder; *provided that* all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

9.19 [**********].

ARTICLE X
DISPUTE RESOLUTION

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Resolution of Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in ARTICLE III ("Governance Disputes") shall be resolved pursuant to ARTICLE III and, to the extent such matters constitute a Financial Dispute, Section 10.4, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply.

10.3 Resolution of Legal Disputes. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts to resolve any Legal Dispute arising under this Agreement by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within [**********] period set forth in Section 3.11(b), either Party may submit in writing the Legal Dispute to the Executive Officers for resolution, specifying the nature

of the Legal Dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred Legal Dispute within the [**********] period set forth in Section 3.11(b). Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such Legal Dispute, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.14.

10.4 Resolution of Financial Disputes.

(a) The Parties shall use all reasonable efforts to resolve any Financial Dispute arising under this Agreement by good faith negotiation and discussion. In the event that the Parties are unable to resolve any such Financial Dispute within the[**********] period set forth in Section 3.11(b), either Party may submit such Financial Dispute in writing to the Executive Officers for resolution, specifying the nature of such Financial Dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith attempt to resolve the referred Financial Dispute within a [**********] period. Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties. In the event the Executive Officers are unable to resolve any such Financial Dispute within such [**********] period, the Parties shall [**********].

(b) [**********].

(i) [**********].

(ii) [**********].

(iii) [**********].

(iv) [**********].

(v) [**********].

10.5 No Waiver. Nothing in this ARTICLE X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI
TRADEMARKS AND CORPORATE LOGOS

11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. For the Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory, unless such Product Trademark is prohibited by applicable Law in any country in the Territory or the JCC determines that, consistent with the Collaboration Purpose, a different Product Trademark should be used in one or more particular countries or Regions to maximize the commercial potential of the Product; *provided that* the Parties and the JCC shall endeavor in good faith to reach agreement on a single Product Trademark for use in the entire Territory. The Product in the Field shall be promoted and sold in the Territory under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.

11.3 Ownership of Product Trademarks. Teva hereby acknowledges and agrees, that, subject to the last sentence of this Section 11.3, [**********]. If (i) applicable Law in any country or region in the Ex-U.S. Territory requires that the holder of the Marketing Approval for the Product in such country or region also own the Product Trademark in such country or region, or (ii) the JCC selects a distinct Product Trademark for use in one (1) or more particular countries or Regions in the Ex-U.S. Territory, then, in each such case, [**********].

11.4 Prosecution and Maintenance of Product Trademark(s). Subject to the last sentence of Section 11.3, [**********] prosecute and maintain the Product Trademark(s) for the Product in the countries of the Territory where the Product is being Commercialized, subject to consultation and cooperation with [**********]. Notwithstanding the foregoing, in the event [**********] elects not to prosecute or maintain any such Product Trademark(s) in any such country in the Territory, [**********] shall provide reasonable prior written notice to [**********] of its intention not to prosecute or maintain any such Product Trademark in such country in the Territory, and [**********] shall have the right to do so on behalf of [**********] for use with the Product, subject to consultation and cooperation with Regeneron. Each Party shall consult with such other Party in good faith, with respect to any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for any Product Trademark in the Territory prior to taking any material action in response thereto. [**********].

11.5 License to the Product Trademark(s).

(a) [**********] hereby grants to [**********] a co-exclusive license in the Territory to use the Product Trademark(s), with the right to grant further sublicenses to any Distributor/Commercial Partner, solely for the purposes of Teva's Development and

Commercialization activities under this Agreement with respect to the Product in the Field in the Territory in accordance with the terms of this Agreement.

(b) During any period of time in which [**********] owns a Product Trademark pursuant to this Agreement, [**********] hereby grants to [**********] (i) a co-exclusive license, with the right to grant further sublicenses to any Person, in the Territory to use such Product Trademark to Develop the Product in the Field in the Territory under the Global Development Plan or any [**********] or Commercialize the Product in the Field solely in the [**********]pursuant to the [**********] and (ii) an exclusive (including with respect to [**********] and its Affiliates) license, with the right to grant further sublicenses to any Person, [**********].

(c) Neither Party shall license (or, as applicable, sublicense) rights to use, or otherwise transfer ownership of the Product Trademark(s) without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Each Party shall only utilize the Product Trademark(s) on approved Promotional Materials, on the Product as needed, or as part of an internet domain name (including for the U.S. or the Ex-U.S. Territory) as agreed upon by the Parties, and on other approved Product-related materials for the Product in the Field in the Territory for the purposes contemplated herein, and all use by a Party or its Affiliates or Distributor/Commercial Partners or, with respect to Regeneron, its sublicensees under Section 11.5(b) of the Product Trademark(s) shall be in accordance with (i) rules established by the JCC and (ii) quality standards established by the JCC that are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register in the Territory any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) in relation to a product that is not the Product, or take any other action that damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5. Once a Product Trademark has been selected by the JCC, the Parties shall enter into a trademark license agreement in order to address the Parties' respective rights and obligations with respect to such license to such Product Trademark in a manner consistent with the provisions set forth herein.

11.6 Use of Corporate Names. The Lead Commercialization Party in a country in the Territory (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include the non-Lead Commercialization Party's name with equal prominence on materials related to the Product in the Field in such country (including package inserts, packaging, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection

with the Product), unless to do so would be prohibited under applicable Laws; *provided that*, in the case of multi-product materials that refer to the Product in the Field as well as other (bio)pharmaceutical products, the prominence of the non-Lead Commercialization Party's name shall be commensurate with the relative prominence of the Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Product in the Field in the Territory during the Term and thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging, internet pages, social media and samples, only for the time period and solely to the extent necessary to exhaust the existing inventory of Product (including packaging materials for the Product) and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld, conditioned or delayed, at least [**********] before dissemination of such materials. Failure of the receiving Party to object within such [**********] period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

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ARTICLE XII
NEWLY CREATED INVENTIONS AND KNOW-HOW AND LICENSE GRANTS

12.1 Ownership of Newly Created Intellectual Property.

(a) Subject to Section 12.4 and except with respect to Product Inventions and Product Trademarks as provided in ARTICLE XI, each Party (and each Party's respective Affiliates) shall exclusively own all right, title and interest in and to any and all intellectual property (including Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement solely by such Party, or its Affiliates or its or their Distributors/Commercial Partners or subcontractors (other than by the other Party or its Affiliates) ("Sole Inventions"). Sole Inventions made solely by or on behalf of Teva or its Affiliates, or its or their Distributors/Commercial Partners or subcontractors (other than by Regeneron or its Affiliates or its or their Distributor/Commercial Partners or subcontractors) are referred to herein as "Teva Sole Inventions", and "Teva Sole Patent Rights" shall mean Patents that solely claim any Teva Sole Inventions. Sole Inventions made solely by or on behalf of Regeneron, its Affiliates or its or their Distributor/Commercial Partners or subcontractors are referred to herein as "Regeneron Sole Inventions".

(b) Subject to Section 12.4 and except with respect to Product Inventions and Product Trademarks as provided in ARTICLE XI, the Parties shall each own an equal, undivided

interest in any and all intellectual property (including Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement jointly by or on behalf of Teva, its Affiliates or its or their Distributor/Commercial Partners or subcontractors, on the one hand, and Regeneron, its Affiliates or its or their Distributor/Commercial Partners or subcontractors, on the other hand ("Joint Inventions").

(c) Each Party shall promptly disclose to the other Party in writing and shall cause its Affiliates, and its and their Distributor/Commercial Partners and subcontractors to so disclose, the conception, discovery, invention, reduction to practice, making, creation or generation of any Joint Inventions.

(d) Notwithstanding Section 12.1(a) and Section 12.1(b), Regeneron (and its Affiliates) shall exclusively own all right, title and interest in and to any and all intellectual property (including Know-How, Patents and copyrights) [**********] ("Product Inventions" and any Patents that claim any Product Inventions, "Product Patent Rights"). Teva shall promptly disclose to Regeneron in writing and shall cause its Affiliates and its and their Distributor/Commercial Partners and subcontractors to so disclose, the conception, discovery, invention, reduction to practice, making, creation or generation of any Product Invention. Teva shall cause all Affiliates and any other Persons who perform activities for it under or in connection with this Agreement or who discover, invent, author or otherwise create intellectual property (including Know-How, Patents and copyrights) on behalf of Teva or its Affiliates under or in connection with this Agreement to assign their rights in any intellectual property resulting therefrom to Teva, except where applicable Law requires otherwise, in which case a suitable license shall be obtained).

(e) Notwithstanding the foregoing in this Section 12.1, (i) for purposes of determining whether an invention (whether or not patentable) is a Teva Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws (or with respect to inventions that are not patentable, the same principles set forth in United States patent laws for patentable inventions) and (ii) for purposes of determining whether a work of authorship (whether or not copyrightable) is a Teva Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship shall be resolved in accordance with United States copyright laws. The Parties shall further ensure that any original work of authorship or artistic work created in connection with this Agreement on behalf of the Parties, their Affiliates or their (or their Affiliates') Distributor/Commercial Partners or subcontractors shall be deemed a "work made for hire," to be included among the Parties' respective intellectual property rights as set forth in Section 12.1(a), Section 12.1(b) or Section 12.1(d), as applicable, and all rights thereto, including all copyrights and moral rights, shall upon their conception or creation exclusively, forever, irrevocably vest in or transfer to Teva or Regeneron as set forth in Section 12.1(a), Section 12.1(b) or Section 12.1(d), as applicable.

(f) To the extent that any right, title or interest in or to any intellectual property (including Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement vests in a Party, by operation of applicable Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party shall, and hereby does, irrevocably assign, and shall cause its Affiliates and any other Person with an obligation to assign any intellectual property (including Know-How, Patents and copyrights) discovered, invented, authored or otherwise created under or in connection with this Agreement to such Party, to assign, to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party to effectuate the ownership set forth in this Agreement. The assigning Party shall perform all acts or refrain from taking action, as required, and shall execute and deliver to the other Party any and all applications, oaths, declarations, affidavits, waivers, assignments and other documents and instruments as shall be deemed necessary or desirable by such other Party to evidence, obtain, perfect, and transfer such intellectual property throughout the world and to render all lawful assistance in connection with the same to effectuate the ownership set forth in this Agreement.

(g) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement, including the terms of this ARTICLE XII, and further shall be governed as follows: [**********].

(h) The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's intellectual property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's intellectual property, other than the rights expressly granted hereunder. Any remuneration payable under applicable Law to an inventor and costs and expenses associated with determining such remuneration in the U.S. shall be shared as [**********] and in the Ex-U.S. Territory shall be borne solely by Teva.

(i) [**********].

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Regeneron Product Patent Rights in the countries and regions in the Territory as determined in accordance with the following sentence. Regeneron shall [**********]. Regeneron shall [**********]. Regeneron shall keep Teva reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of the Regeneron Product Patent Rights. Regeneron shall provide Teva with copies of, and an opportunity to review and comment on, any material filings (before the filing thereof) and correspondence with applicable patent offices for such Patents. The Parties shall discuss in good faith the incorporation of Teva's

proposed comments on such material filings. If Regeneron desires to abandon or cease prosecution or maintenance of any Regeneron Product Patent Rights in a country in the Territory (including by declining to file a continuation or divisional application prior to issuance of a parent Patent or not validating any Patent in any country in the Territory), or not to seek Patent protection for any Product Inventions, Regeneron shall promptly notify Teva of such intention. In such case, no later than [**********] after such notice from Regeneron intending to abandon or cease prosecution or maintenance, upon Teva's written election, Teva shall have the right to assume prosecution and maintenance of such Patent in Regeneron's name; *provided, however*, that (i) Teva shall have no right to assume prosecution and maintenance of such Patent if, [**********]. In such case, Teva shall keep Regeneron reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Patent, including content, timing and jurisdiction of the filing of such Patent. Teva shall provide Regeneron with copies of, and an opportunity to review and comment on, any material filings (before the filing thereof) and correspondence with applicable patent offices for such Patent. The Parties shall discuss in good faith the incorporation of Regeneron's proposed comments to avoid any inconsistency with Regeneron's global Patent strategy. If Teva does not provide such election within [**********] after such notice from Regeneron, Regeneron may, at its sole and absolute discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent (including by declining to file a continuation or divisional application prior to issuance of a parent Patent or not validating any Patent in any country); *provided that* Regeneron will notify Teva as described above if Regeneron elects to so continue prosecution and maintenance and thereafter desires to abandon or cease prosecution or maintenance of such Patent.

(b) Teva shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Teva Sole Patent Rights in the countries and regions in the Territory determined in accordance with the following sentence. Teva shall [**********]. Teva shall [**********]. Teva shall keep Regeneron reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of the Teva Sole Patent Rights. Teva shall provide Regeneron with copies of, and an opportunity to review and comment on, any material filings (before the filing thereof) and correspondence with applicable patent offices for such Patents. The Parties shall discuss in good faith the incorporation of Regeneron's proposed comments on such material filings. If Teva desires to abandon or cease prosecution or maintenance of any Teva Sole Patent Rights (including by declining to file a continuation or divisional application prior to issuance of a parent Patent or not filing for or validating any Patent in any country in the Territory), Teva shall promptly notify Regeneron of such intention. In such case, no later than [**********] after such notice from Teva intending to abandon or cease prosecution or maintenance, upon Regeneron's written election, Regeneron shall have the right to assume prosecution and maintenance of such Patent in Teva's name; *provided, however*, that Regeneron shall have no right to assume prosecution and maintenance of such Patent if, [**********]. In such case, Regeneron shall keep Teva

reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Patent, including content, timing and jurisdiction of the filing. Regeneron shall provide Teva with copies of, and an opportunity to review and comment on, any material filings (before the filing thereof) and correspondence with applicable patent offices for such Patent. The Parties shall discuss in good faith the incorporation of Regeneron's proposed comments to avoid any inconsistency with Teva's global Patent strategy. If Regeneron does not provide such election within [**********] after such notice from Teva, Teva may, at its sole and absolute discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent (including by declining to file a continuation or divisional application prior to issuance of a parent Patent or not validating any Patent in any country); *provided that* Teva will notify Regeneron as described above if Teva elects to so continue prosecution and maintenance and thereafter desires to abandon or cease prosecution or maintenance of such Patent.

(c) Regeneron shall have the first right, but not the obligation, to prepare, file, prosecute and maintain any [**********] anywhere in the world. Regeneron shall consult with and keep Teva reasonably informed regarding the status of such activities, including by providing Teva a reasonable opportunity to review and comment on any material filings (before the filing thereof) and correspondence with applicable patent offices for such Patents. Teva and Regeneron shall agree in advance on a general patent prosecution strategy for [**********] addressing, among other things, the scope of claims to be pursued and the countries in which [**********] will be filed and prosecuted. [**********]. If Regeneron desires to abandon or cease prosecution or maintenance of any [**********] (including by declining to file a continuation or divisional application prior to issuance of a parent Patent or not validating any Patent in any country or not seeking Patent protection for any [**********], Regeneron shall promptly notify Teva of such intention. In such case, no later than [**********] after such notice from Regeneron intending to abandon or cease prosecution or maintenance, upon Teva's written election, Teva shall have the right to assume prosecution and maintenance of such [**********] in the name of both Parties. In such case, Teva shall keep Regeneron reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Patent, including content, timing and jurisdiction of the filing of such Patent. Teva shall provide Regeneron with copies of, and an opportunity to review and comment on, any material filings (before the filing thereof) and correspondence with applicable patent offices for such Patent. The Parties shall discuss in good faith the incorporation of Regeneron's proposed comments to avoid any inconsistency with Regeneron's global Patent strategy. If Teva does not provide such election within [**********] after such notice from Regeneron, Regeneron may, at its sole and absolute discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent (including by declining to file a continuation or divisional application prior to issuance of a parent Patent or validating any Patent in any country); *provided that* Teva will notify Regeneron as

described above if Teva elects to so continue prosecution and maintenance and thereafter desires to abandon or cease prosecution or maintenance of such Patent.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Teva Sole Patent Rights, Regeneron Product Patent Rights and [**********] pursuant to this Section 12.2, including, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Patents that such Party has elected not to pursue.

(e) (1) Regeneron shall have the sole right, in its discretion to prepare, file, prosecute, and maintain Regeneron Background Patent Rights and Regeneron Manufacturing Patents in the Territory [**********], and all costs and expenses incurred in connection therewith (including any Out-of-Pocket Costs incurred by Regeneron) shall be Regeneron's sole responsibility and not included in any cost sharing between the Parties under this Agreement or any Ancillary Agreement (including as Other Shared Expenses) and (2) Teva shall have the sole right, in its discretion to prepare, file, prosecute, and maintain Teva Background Patent Rights worldwide and Regeneron shall have no rights in connection therewith, and all costs and expenses incurred in connection therewith (including any Out-of-Pocket Costs incurred by Teva) shall be Teva's sole responsibility and not included in any cost sharing between the Parties under this Agreement or any Ancillary Agreement (including as Other Shared Expenses).

(f) Except as provided in Section 12.2(e), all Out-of-Pocket Costs incurred in the preparation, filing, prosecution and maintenance of any Teva Sole Patent Rights, Regeneron Product Patent Rights, and [**********] in the Territory shall be [**********].

12.3 Interference, Opposition, and Other Administrative Patent Proceedings.

(a) Each Party will notify the other within [**********] of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition, post-grant review, inter-partes review, derivation proceeding, supplemental examination, reissue, reexamination, or other similar administrative Patent proceedings relating to Regeneron Product Patent Rights, Teva Sole Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms; [**********].

(b) (1) Regeneron shall have the sole right in its discretion to make all determinations with respect to the Regeneron Background Patent Rights and Regeneron Manufacturing Patents and Teva shall have no rights in connection therewith, and all costs and expenses incurred in connection therewith (including any Out-of-Pocket Costs incurred by Regeneron) shall be Regeneron's sole responsibility and not included in any cost sharing between the Parties under this Agreement or any Ancillary Agreement (including as Other Shared Expenses), and (2) Teva shall have the sole right in its discretion to make all determinations with respect to the Teva Background Patent Rights and Regeneron shall have no rights in connection therewith, and all costs and expenses incurred in connection therewith (including any Out-of-Pocket Costs incurred by Teva) shall be Teva's sole responsibility and not included in any cost sharing between the Parties under this Agreement or any Ancillary Agreement (including as Other Shared Expenses).

(c) Except as provided in Section 12.3(b), all Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue, post-grant review, reissue, reexamination or other similar administrative Patent proceedings relating to the Regeneron Product Patent Rights, Teva Sole Patent Rights or Joint Patent Rights in the Territory shall be [**********].

12.4 License Grants; Sublicenses.

(a) Subject to the terms and conditions of this Agreement and any License to which Teva or any of its Affiliates is a party, Teva hereby grants to Regeneron the nontransferable (except as permitted by Section 20.8), royalty-free, fully paid up, co-exclusive (with Teva and its Affiliates) right and license under (i) Teva Sole Inventions, Teva Sole Patent Rights, and Teva's interest in the Joint Inventions and Joint Patent Rights, to make, have made, use, import, develop, sell and offer to sell the Product and other Competing Products for use in the Field worldwide and (ii) Teva Background Patent Rights to make, have made, use, import, develop, sell and offer to sell the Product for use in the Field worldwide (but with respect to outside of the Territory, only for the benefit of the Product within the Territory). Subject to Section 12.4(c), Regeneron will have the right to sublicense any of its rights under this Section 12.4(a) without the prior written consent of Teva.

(b) Rights Granted to Teva. Subject to the terms and conditions of this Agreement and any License to which Regeneron or any of its Affiliates is a party, during the Term, Regeneron on behalf of itself and its Affiliates, hereby grants to Teva, the nontransferable (except as permitted by Section 20.8), right and license, under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions and Joint Patent Rights:

(i) to Commercialize (but not Manufacture) the Product for use in the Field solely in the Ex-U.S. Territory (including under the Ex-U.S. Territory Commercialization Plan and any Country/Region Commercialization Plan), which

license shall be exclusive (even as to Regeneron and its Affiliates) and payment-bearing (pursuant to Section 9.6);

(ii) to Commercialize (but not Manufacture) the Product for use in the Field in the United States (including under the U.S. Commercialization Plan), which license shall be co-exclusive (with Regeneron and its Affiliates) and payment-bearing (pursuant to Section 9.5);

(iii) to Develop (but not Manufacture) the Product for use in the Field solely in the Ex-U.S. Territory under the Ex-U.S. Territory Development Plan, which license shall be non-exclusive;

(iv) to perform the Development activities allocated to Teva under the Global Development Plan or any Regeneron Additional Trial Plan, as applicable, solely in the Territory, which license shall be non-exclusive; and

(v) to conduct Teva Additional Trials for the Product solely in the Territory under any Teva Additional Trial Plan, which license is non-exclusive.

Teva will have the right to (x) sublicense (through multiple tiers) any of its rights under this Section 12.4(b), (1) with respect to the Ex-U.S. Territory other than the Major Market Countries [**********] and [**********], with Regeneron's consent, [**********], and (2) with respect to the Major Market Countries [**********], with the prior written consent of Regeneron, [**********], in each case subject to Section 12.4(c) and (y) subcontract and utilize one or more Distributor/Commercial Partners as contemplated by Sections 4.1, 4.2 and 4.3, as applicable.

(c) Sublicenses. Each sublicense granted to a Third Party by Regeneron pursuant to Section 12.4(a) or Teva pursuant to Section 12.4(b), (the Party granting such sublicense, the "Granting Party") will be set forth in a binding written agreement with such Third Party (each, a "Sublicense Agreement," and such Third Party to which such sublicense is granted, the "Sublicensee") will be subject and subordinate to this Agreement and will contain provisions consistent with the terms and conditions of this Agreement. Each such Sublicense Agreement will contain the following provisions: [**********]. The Granting Party shall remain responsible and liable for the acts and omissions of its Sublicensees and the compliance by its Sublicensees with applicable terms and conditions set forth in this Agreement and any applicable License. The Granting Party will forward to the other Party a complete copy of each applicable fully executed Sublicense Agreement (and any amendment(s) thereto) within ten (10) days of the execution of such Sublicense Agreement. For clarity, in the case of any Distributor/Commercial Partner or subcontractor that does not receive a sublicense of rights as contemplated by Section 12.4(a) or Section 12.4(b), as applicable, this Section 12.4(c) shall not apply (and the use of such Distributor/Commercial Partner

or subcontractor will not be deemed a "sublicense" hereunder) but Regeneron or Teva, as applicable, shall comply with Section 4.1, Section 4.2 and Section 4.3, as applicable.

12.5 No Implied License; Retention of Rights. Except as expressly provided in Section 11.5 or Section 12.4, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patents, Know-How, or Party Information, either expressly or by implication, estoppel or otherwise. [**********]. For clarity, Regeneron expressly retains the right to grant licenses or other rights to any of its Affiliates or to any Third Parties under any of Regeneron's retained rights. Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted or reserved to Teva pursuant to any other term or condition of this Agreement, Teva hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its licensors, (sub)licensees and subcontractors and Distributor/Commercial Partners) all right, title and interest in and to the Teva Background Patent Rights, the Teva Background Know-How, and Teva's interests in and to Joint Patent Rights and Joint Inventions, in each case, for purposes of: (i) performing its and their obligations under and in compliance with this Agreement, including to conduct the Development activities for which it is responsible under the Ex-U.S. Territory Development Plan and any Teva Additional Trial Plan; (ii) (subject to Section 2.6) developing, obtaining and maintaining Approvals for and manufacturing, commercializing and otherwise exploiting any product, other than the Product, in any field (including the Field) anywhere in the world; and (iii) exercising its and their rights under this Agreement, including to (A) Develop, obtain and maintain Approvals for, and Commercialize the Product in the Ex-U.S. Territory in compliance with the terms of this Agreement and (B) settle any enforcement action or proceeding (including any counterclaim in any such action or proceeding), declaratory judgment action or similar action or claim, or any other litigation or proceeding involving an allegation of infringement or other violation of intellectual property rights, including by granting licenses or other rights under Patents to Third Parties in connection therewith, in each case in compliance with ARTICLE XIII. For clarity, Teva expressly retains the right to grant licenses or other rights to any of its Affiliates or to any Third Parties under any of Teva's retained rights.

12.6 Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this ARTICLE XII, neither Party shall have the right to make an election under 35 U.S.C. 102(c) when exercising its rights under this ARTICLE XII without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. 100(h).

12.7 Patent Term Extension and Supplementary Protection Certificate. As between the Parties, (a) [**********] to apply for patent term extensions in the U.S. and any other jurisdictions in which a limited number of Patents may be extended for a product, including with respect to extensions pursuant to 35 U.S.C. §156 et. seq., [**********] and (b) with respect to any jurisdiction in the Ex-U.S. Territory in which there is no limit on the number of Patents that may be extended for a product, (i) each Party shall have final decision-making rights regarding any such extensions or certificates with respect to Patents (other than [**********]) that it owns or Controls (other than pursuant to the licenses granted in Section 12.4) in the Ex-U.S. Territory that are within the Regeneron Product Patent Rights or Teva Sole Patent Rights; [**********]. Each Party shall provide the other Party prompt and reasonable assistance, as requested by such other Party, including by taking such action as is required of the Approval holder under any applicable Law to obtain such extension or supplementary protection certificate. All Out-of-Pocket Costs incurred by the Parties or their Affiliates in connection with any such extensions or certificates in the Territory shall be [**********].

12.8 Marketing Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any Major Market Country, (a) a Party(ies) has the exclusive legal right, by means of rights granted by a Governmental Authority in such country (other than with respect to any Patents), to Commercialize the Product in the Field in such Major Market Country and (b) no generic equivalent of the Product in the Field may be marketed in such Major Market Country.

12.9 Existing Patents. Teva acknowledges that Regeneron Patent Rights existing as of the Effective Date are already in the process of being prosecuted and maintained, and [**********].

12.10 Internal Costs. For clarity, each Party shall be responsible for any internal costs incurred by such Party or its Affiliates under this ARTICLE XII.

ARTICLE XIII
INTELLECTUAL PROPERTY LITIGATION AND LICENSES

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a [**********] in the Territory ("Infringement"), including by virtue of a biosimilar competitor's activities in the Territory with respect to the Product, including any regulatory filing based on Section 351(k) of the Public Health Service Act (42 U.S.C. 262) or Article 10(4) of the Directive 2001/83/EC or any other similar regulation promulgated by the FDA, EMA or by other applicable similar governmental regulatory authorities or other actual

or potential infringement by a biosimilar or potential biosimilar competitor anywhere in the Territory ("Biosimilar Infringement"), the Party that became aware of such Infringement shall promptly notify the other Party in writing of the same and shall provide such other Party with all available evidence under such Party's Control supporting such Infringement.

(b) With respect to any Infringement, [**********].

(c) [**********].

(d) If either Party commences an enforcement action in the Territory pursuant to Section 13.1(b) or Section 13.1(c), as applicable (such Party "Enforcing Party"), the other Party (the "Non-Enforcing Party") [**********].

(e) [**********].

(f) [**********].

(g) [**********].

(h) All Out-of-Pocket Costs incurred in connection with any litigation or other proceeding under Section 13.1 related to activities in the Territory shall be [**********]. The amount of any recovery from any litigation or other proceeding under this Section 13.1 (by court award, settlement or other resolution) shall first be used to pay reasonable costs and expenses, including attorneys' fees, relating to such litigation or other proceedings (including, for clarity, any Out-Of-Pocket Costs incurred by the Non-Enforcing Party pursuant to the proviso in the immediately preceding sentence), and any remainder after such reimbursement is made shall be [**********].

(i) As between the Parties, other than with respect to any Infringement, each Party shall retain all enforcement rights with respect to any Patents solely owned by such Party or any of its Affiliates (or with one or more Third Parties, but not the other Party or any of its Affiliates) worldwide and the other Party shall have no rights in connection with any such enforcement.

(j) [**********].

(k) Notwithstanding the foregoing, [**********].

13.2 Patent Marking. Unless otherwise mutually agreed to by the Parties in writing, each Party shall comply with the Patent marking statutes in each country in which the Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates or its or their Distributor/Commercial Partners.

13.3 Third Party Infringement Claims; New Licenses.

(a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of the Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory ("Third Party Infringement Claim"), then such Party shall promptly notify the other Party in writing of this allegation. [**********].

(b)

(i) [**********].

(ii) [**********].

(c)

(i) Each Party will notify the other if such Party becomes aware of any Patent of a Third Party [**********] that (x) is not Controlled by either Party and (y) could arguably be infringed by the Development, Manufacture or Commercialization of the Product in the Territory under this Agreement ("Third Party Patent"). [**********].

(ii) [**********].

(d) In addition to and not in lieu of any obligations of the Parties in Sections 13.3(a) through (c), if a Party shall become engaged in or participate in any suit or other proceeding described in this Section 13.3, the other Party shall cooperate, and shall cause its and its Affiliates' employees to cooperate, with such Party in all reasonable respects in connection therewith, including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the other, at no cost to the other (other than reimbursement of actually incurred, reasonable out-of-pocket travel and lodging expenses), such employees who may be helpful with respect to such suit, investigation, claim, interference or other proceeding.

(e) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs incurred for any suit or proceeding in the Territory in connection with any suit or proceeding referred to in this Section 13.3 (including existing proceedings) shall be [**********].

(f) Subject to Section 13.3(g), such license fees, milestones, royalties and other payments under Licenses to the extent attributable to, and based on, the Development, Manufacture or Commercialization of the Product in the Territory shall be [**********] in the Quarter in which such license fees, milestones, royalties or other payments were incurred by a Party, [**********].

(g) Royalties under any Existing Agreement attributable to, and based on, the Development of the Product for, Manufacture of the Product for sale in, or Commercialization of the Product in, the Field in the United States shall be [**********]. Regeneron shall be solely responsible for any royalties or other similar contingent payments (e.g., milestones) under any Existing Agreement attributable to, and based on, the Development of the Product for, Manufacture of the Product for sale in, or Commercialization of the Product in, the Field in the Ex-U.S. Territory, [**********].

(h) If a Party or its Affiliate seeks to enter into any potential License (other than a Platform License) after the Effective Date, such Party will [**********].

(i) [**********].

(j) Notwithstanding the foregoing, [**********].

13.4 Internal Costs. For clarity, each Party shall be responsible for any internal costs incurred by such Party or its Affiliates under this ARTICLE XIII.

ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with such Party's Accounting Standards) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement (including the utilization of FTEs, the determination of the Commercial Overhead Charge, and the allocation of personnel under this Agreement). To the extent additional information is reasonably required to comply with Regeneron's obligations under the Existing Agreements or any License or with Teva's obligations under any License, the Parties shall work together in good faith to timely compile and produce such additional information. Each Party shall keep its books of record and account to the extent related to this Agreement in a readily available and organized form to allow an independent auditor to verify the accuracy of all financial, accounting and numerical information provided in an efficient manner. To the extent an audited Party is not in compliance with the previous sentence, the audited Party shall be responsible for any additional fees charged by the independent auditor to the auditing Party as a result of additional time spent by the independent auditor assembling or organizing such information. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of the employees of the Party whose books are being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its own cost and expense), upon no less than [**********] advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Calendar Year, to have the books and records of the other Party and its Affiliates maintained pursuant to Section 14.1 to the extent relating to this Agreement for the preceding [**********] audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all costs and expenses, financial, accounting and numerical information and calculations provided, including Commercial Supply Costs, Development Costs, Development Supply Costs, Field Force Costs, Manufacture Costs, Non-Field Force Commercial FTE Costs, Other Shared Expenses, Shared Commercial Expenses, Additional Trial Costs, and payments made, under this Agreement; *provided that* no period may be subjected to audit more than [**********] unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within [**********]

of delivery. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy of amounts incurred during any year of more than [**********], the audited Party shall also reimburse the other Party for the costs and expenses of such audit (with the cost and expense of the audit to be paid by the auditing Party in all other cases). The Parties shall cause such accountants to enter into a reasonably acceptable confidentiality agreement with the audited Party and obligating such firm to retain all such financial information in confidence pursuant to terms no less stringent than those set forth in ARTICLE XVI. Such accountants shall only disclose to the Party requesting the audit a summary of its review and findings and shall not disclose to the Party requesting the audit or any Third Party any information reasonably labeled by the audited Party as being confidential or competitively sensitive or proprietary information.

(c) If any examination or audit of the records described above discloses an overpayment or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 14.2(d), (i) the Party that underpaid shall pay any amounts due plus, if such underpayment is the underpaying Party's fault, interest thereon at the Default Interest Rate accruing from the date of such underpayment, or (ii) the Party that received an overpayment shall refund such overpayment plus, if such overpayment is the fault of the Party refunding such payment, interest thereon at the Default Interest Rate accruing from the date of such overpayment, in each case ((i) and (ii)) within thirty (30) days after receipt of the written results of such audit.

(d) Subject to the first (1^{st}) sentence of Section 14.2(b), any disputes with respect to the results of any audit conducted under this Section 14.2 shall be subject to dispute resolution in accordance with ARTICLE X.

14.3 GAAP/IFRS. Except as otherwise provided herein, all of a Party's costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with such Party's Accounting Standards, as generally and consistently applied.

ARTICLE XV
REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 Due Organization, Valid Existence and Due Authorization; Financial Capability. Each Party represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the applicable Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement; (c) it has full corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (d) it has taken all corporate action necessary to

enter into and perform this Agreement; (e) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents or any requirement of applicable Laws or regulations; (f) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (g) the individuals executing this Agreement for such Party have been duly authorized to execute and deliver this Agreement on behalf of such Party; (h) to such Party's knowledge, neither it nor any of its Affiliates have materially violated any applicable Anti-Corruption Laws with respect to the Territory; (i) all necessary consents, approvals and authorizations of all Governmental Authorities and other persons or entities required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and (j) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder. As used in ARTICLE XV, "knowledge" or "has knowledge" means, [**********].

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, hearing, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator or Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 No Conflict. Except with respect to matters under [**********], each Party represents and warrants to the other Party that, as of the Effective Date, it has not entered into any agreement with any Third Party that is in material conflict with the licenses and other rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the licenses and other rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or materially adversely affect the license and other rights granted to the other Party under this Agreement, and its performance and execution of this Agreement will not result in a material breach of any other contract to which it is a Party.

15.4 Additional Regeneron Representations and Warranties. Regeneron additionally represents and warrants to Teva that, except as disclosed on Schedule 15.4 hereto, as of the Effective Date:

(a) Regeneron or its Affiliate(s) owns all right, title and interest in and to all Regeneron Product Patent Rights in existence as of the Effective Date;

(b) Regeneron has sufficient legal or beneficial title, ownership or license, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind, as necessary to sell and transfer the Product to Teva as contemplated by this Agreement;

(c) to Regeneron's knowledge there is no pending litigation alleging, and Regeneron has not received written notice that alleges, that any of Regeneron's making, using, selling, offering to sell, or importing of the Product has violated, or would violate, a Valid Claim of an issued and unexpired Patent of any Third Party in the Territory;

(d) [**********];

(e) to Regeneron's knowledge, the Development and Manufacture of the Product as of the Effective Date has not constituted or involved the misappropriation of the trade secrets of a Third Party;

(f) Regeneron and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Regeneron Know-How and Manufacturing Information that Regeneron in its reasonable discretion deems to be necessary for Teva to Develop or Commercialize the Product in the Field in the Territory and in accordance with this Agreement and that constitutes trade secrets under applicable Laws (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring such employees, consultants and independent contractors to maintain the confidentiality of such Regeneron Know-How and Manufacturing Information) and, to Regeneron's knowledge, such Regeneron Know-How has not been disclosed to any Third Party except pursuant to such confidentiality agreements and there has not been a breach by any party to such confidentiality agreements;

(g) to Regeneron's knowledge, the issued and unexpired Regeneron Product Patent Rights as of the Effective Date are not invalid or unenforceable, in whole or part; Schedule 1.142 lists all Patents owned or in-licensed by Regeneron or any of its Affiliates as of the Effective Date that qualify as Regeneron Product Patent Rights based on the definition thereof; no licenses or other rights have been granted to any Third Party under any Regeneron Product Patent Rights to commercialize any Competing Product in the Territory; and no licenses or other rights

have been granted to a Third Party as of the Effective Date to Commercialize the Product in the Territory;

(h) Regeneron has not received any written notice of any threatened litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or the Regeneron Manufacturing Patents or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Product Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings;

(i) to Regeneron's knowledge, neither Regeneron nor any officer, employee or agent of Regeneron has knowingly made an untrue statement of a material fact to any Regulatory Authority in the Territory with respect to the Product or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority in the Territory with respect to the Product, in each case, that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory;

(j) Except with respect to the agreements (and payments thereunder to the extent) set forth in Schedule 15.4(j), neither Regeneron nor any of its Affiliates is a party to any agreement (including any Existing Agreement) as of the Effective Date that imposes a royalty or other similar contingent payments (e.g. milestones) on the Development or Commercialization of the Product (as it exists as of the Effective Date) in the Territory; and

(k) Regeneron and its Affiliates have not received any written notice of material breach of any Existing Agreement or other agreement specifically relating to the Manufacture of the Product to which Regeneron or any of its Affiliates is party from the applicable counterparty thereto, and to Regeneron's knowledge there have been no acts or omissions by Regeneron or its Affiliates that constitute a material breach of an Existing Agreement that would result in the actual termination of such Existing Agreement, that would, in either case, prevent Regeneron from meeting its Development, Commercialization or Manufacturing obligations, or granting to Teva its licenses or other rights, under this Agreement.

(l) [**********].

15.5 Additional Teva Representations and Warranties. Teva additionally represents and warrants to Regeneron that, as of the Effective Date, (a) Teva has no knowledge of any pending filing, complaint, hearing, matter or action against or involving either Teva or its Affiliates with any Governmental Authority that could be reasonably anticipated to have a material

adverse effect on its ability to obtain Approvals for the Product in any country or region of the Ex-U.S. Territory, and (b) there are no Teva Background Patent Rights.

15.6 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.7 Mutual Covenants. Each Party hereby covenants to the other Party as follows: (a) except (in the case of Regeneron) with respect to matters under [**********], it will not during the Term grant any right or license, or make any assignment or other transfer to any Third Party in the Territory that would be inconsistent with or in conflict with or in derogation of the licenses or other rights granted to the other Party under this Agreement or the obligations of such Party under this Agreement; (b) except with respect to the Joint Patent Rights, neither Party will use the Patents or Know-How of the other Party outside the scope of the licenses and other rights granted to it under this Agreement; (c) in the course of the Development, Manufacture (with respect to Regeneron) or Commercialization of the Product in the Field under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority and (d) it will have a written agreement with all of its employees and contractors who may participate in the conduct of the Collaboration or receive confidential information hereunder assigning to such Party ownership of all intellectual property rights created in the course of their employment or provision of services, as applicable.

15.8 Business Ethics.

(a) Each Party agrees to conduct its activities under this Agreement in a manner that is consistent with law, including the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism (collectively, "Anti-Corruption Laws"), and good business ethics.

(b) Each Party shall not, directly or indirectly, in connection with its activities under this Agreement pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything of value (collectively, a

"Payment") to any official or employee of any government, or any department, agency, or instrumentality thereof; political party or political party official; official or employee of any international public organizations; candidates for public office; representatives of other businesses; health care professionals; or persons acting on behalf of any of the foregoing (collectively, "Officials") where such Payment would constitute a violation of any Anti-Corruption Law. In addition, regardless of legality, each Party shall not make any Payment, directly or indirectly, in connection with its activities under this Agreement, to any Official if such Payment is for the purpose of improperly influencing or rewarding any act or decision of such Official, or (ii) inducing such Official to do or omit to do any act in violation of his or her lawful duty, or (iii) improperly inducing such Official to use its or his influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, or (iv) securing any improper advantage for either Party. Each Party acknowledges and agrees that none of it, or any of its Affiliates or its or their respective officers, directors, employees, agents and representatives (collectively, "Representatives") is authorized to waive compliance with the provisions of this Section 15.8 and that each Party will be solely responsible for its compliance with the provisions of this Section 15.8 and the Anti-Corruption Laws irrespective of any act or omission of the other Party or any of its Affiliates, Distributor/Commercial Partners, or subcontractors or its or their respective Representatives. Each Party's failure to abide by the provisions of this Section 15.8 shall be deemed a material breach of this Agreement and without prejudice to any other rights or remedies that may be available to the non-breaching Party under this Agreement or in law or equity.

(c) Each Party shall promptly notify the other Party upon becoming aware of and shall keep such Party reasonably apprised of, (i) any allegation or violation of, or any notice, subpoena, demand, or other communication (oral or written) from any governmental authority regarding such Party's actual, alleged, or possible failure to comply with, any Anti-Corruption Laws or any other Laws by such Party or any of its Affiliates or those acting on such Party's behalf, (ii) any confirmed or corroborated violation of Anti-Corruption Laws or any other Laws that are the result of an internal inquiry, in each case of (i) and (ii), in connection with the matters that are the subject of this Agreement and the performance by such Party of its obligations hereunder; and (iii) the occurrence of any fact or event that would render any representation, warranty, covenant, or undertaking in Section 15.8(a) or (b) incorrect or misleading. Following such notification, the notifying Party shall keep the other Party reasonably apprised of the matters described in this Section 15.8(c) throughout the duration of such matters.

(d) [**********].

15.9 [**********].

ARTICLE XVI
CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Teva and Regeneron acknowledges (subject to Section 16.1(b) and the provisions of ARTICLE XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by or on behalf of the other Party or its respective Affiliates or its or their Distributor/Commercial Partners or subcontractors pursuant to this Agreement is confidential and proprietary to such other Party or its Affiliates or its or their Distributor/Commercial Partners or subcontractors. Furthermore, Teva acknowledges and agrees (subject to the further provisions of this ARTICLE XVI) that all Product Information and Regeneron's or its Affiliates' Manufacturing Information is confidential and proprietary to Regeneron and its Affiliates (and, irrespective of the Person who first disclosed it, Regeneron shall be deemed to be the disclosing Party and Teva shall be deemed to be the receiving Party with respect thereto). Subject to the further provisions of this ARTICLE XVI, each of Teva and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates or its or their Distributor/Commercial Partners or subcontractors) and, solely with respect to Teva, all Product Information in confidence during the Term and for a period of ten (10) years thereafter; *provided that* such obligations with respect to trade secrets shall survive indefinitely (ii) use such Party Information of the other Party (or its Affiliate) and, solely with respect to Teva, Product Information solely for the purpose of exercising its rights and performing its obligations hereunder. [**********]. Each of Teva and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliates or Distributor/Commercial Partners or subcontractors) or, [**********] to any Third Party, except (A) to its employees, agents, consultants or any other Person under its authorization; *provided that* such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties[**********], (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided in Section 16.1(a), the restrictions provided in this ARTICLE XVI shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; *provided that* this clause (ii) shall not apply with respect to Product Information generated by Teva or any of its Affiliates or Distributor/Commercial Partners; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information and not with respect to

Product Information disclosed to Teva or any of its Affiliates by a Distributor/Commercial Partner that is generated by the Distributor/Commercial Partner; or (iv) similar in nature to the purported Party Information or Product Information but has been independently created outside of this Agreement, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or Product Information.

(c) Notwithstanding anything provided in Section 16.1(a), each Party may use or disclose Party Information of the other Party and Product Information [**********] to the extent that use or disclosure is (i) necessary to file, prosecute or defend Patents or Patent applications for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; *provided that* reasonable measures have been taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law; (ii) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the receiving Party's (or its parent entity's) securities are traded), or court order to be disclosed; *provided that* the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable; and *provided, further*, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information that is required by Governmental Authority, applicable Law or court order to be disclosed; (iii) to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information; (iv) to the Regulatory Authorities as required in connection with obtaining or maintaining any Approval of the Product in the Field in the Territory pursuant to the terms of this Agreement; *provided that* reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with applicable Law; or (v) required under a License or, with respect to Regeneron, under an Existing Agreement [**********]; *provided that* the recipient is subject in writing to substantially the same confidentiality obligations as the Parties.

(d) Notwithstanding anything provided in this Section 16.1 or elsewhere in this Agreement, each Party and its Affiliates shall have the right to use and disclose any Product Information directly related to the Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by applicable Law.

(e) Without limitation of any of the foregoing [**********].

16.2 Injunctive Relief. The Parties hereby acknowledge and agree that the rights of the Parties under this ARTICLE XVI are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this ARTICLE XVI, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this ARTICLE XVI, then, in addition to any other remedy that may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged Party will be entitled to seek in any court of competent jurisdiction.

16.3 Publication of Product or Party Information.

(a) Subject to Section 16.1 with respect to [**********], Regeneron may publish or present the results of any research or development of [**********]. Regeneron shall provide Teva with an advance copy of any proposed publication or summary of any proposed oral presentation or poster relating to [**********] prior to submission for publication or disclosure for Teva's review and comment. Teva shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to (i) prevent any specific, material negative effect to it or the Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material negative effect), or (ii) to enable Teva to obtain Patent protection if it deems necessary. Regeneron will give good faith consideration to comments made by Teva with respect to such publications. If requested by Teva, Regeneron will delay or prevent such disclosure or publication as reasonably proposed by Teva. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a Patent application(s) or application(s) for a certificate of invention on the information involved.

(b) Subject to Section 16.1 with respect to [**********], Teva may, with the prior written consent of Regeneron, which consent may not be unreasonably withheld, conditioned or delayed, publish or present any clinical data resulting from clinical trials sponsored by Teva pursuant to the Ex-U.S. Territory Development Plan or any [**********] conducted by Teva. Teva shall provide Regeneron with an advance copy of any proposed publication or summary of any proposed oral presentation or poster prior to submission for publication or disclosure for Regeneron's review and comment. Without limitation of Regeneron's right to consent, Regeneron shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to (a) prevent any specific, material negative effect to it or the Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material negative effect), or (b) to enable Regeneron to obtain Patent protection if it deems it necessary.

Teva shall not unreasonably reject such comments, and, if requested by Regeneron, shall delay or prevent such disclosure or publication as reasonably proposed by Regeneron. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a Patent application(s) or application(s) for a certificate of invention on the information involved.

16.4 Disclosures Concerning this Agreement. The Parties agree to issue the joint press release in substantially the form attached hereto as Exhibit D promptly following the Effective Date. Teva and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any actions or activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's securities (or the securities of its parent entity, including, in the case of Regeneron, of Parent)) are traded and further including, for the avoidance of doubt, the rules and regulations of the United States Securities and Exchange Commission to the extent applicable to a Party (or its parent entity, including, in the case of Regeneron, Parent); *provided that* the Party intending to disclose such information shall (a) use reasonable efforts to (i) provide the other Party advance notice of such required disclosure and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and (ii) assist the other Party to protect such information and (b) limit the disclosure to the information that is required, in the reasonable judgment of the disclosing Party, to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements that incorporate information concerning this Agreement or

any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure that was previously disclosed under the terms of this Agreement or that contains only non-material factual (non-financial) information regarding the Collaboration. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's securities (or the securities of its parent entity, including, in the case of Regeneron, of Parent)) are traded and further including, for the avoidance of doubt, the rules and regulations of the United States Securities and Exchange Commission to the extent applicable to a Party (or its parent entity, including, in the case of Regeneron, Parent) or in connection with the enforcement of this Agreement or adjudication of any Financial Dispute, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any terms of this Agreement that have not been previously disclosed publicly pursuant to this ARTICLE XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; except for disclosures to Third Parties for a reasonable business purpose that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least ten (10) years (or indefinitely with respect to trade secrets). The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Product in the Field in the Territory. Regeneron acknowledges that Teva (or its parent entity), and Teva acknowledges that Parent, is a publicly traded company and, as such, is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties (or, its parent entity, including in the case of Regeneron, Parent) may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party (or, its parent entity, including in the case of Regeneron, Parent) will be entitled to make such filing, but the Parties shall cooperate with each other and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon and upon the written request of the non-filing Party, will request an appropriate extension of the term of the confidential treatment period (provided that, in the case of Regeneron and Teva, "filing Party" shall mean, for purposes of this sentence, Parent and Teva (or its parent entity), respectively). For the avoidance of doubt, each Party will be responsible for its own legal and other costs in connection with any filing governed by the terms of this Section 16.4.

ARTICLE XVII
INDEMNITY

17.1 Indemnity and Insurance.

(a) Teva will defend, indemnify and hold harmless Regeneron, its Affiliates and its and their respective officers, directors, employees, Distributor/Commercial Partners, distributors outside of the Territory [**********], and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' or experts' fees and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement (a "Third Party Claim") against a Regeneron Indemnitee that is due to or based upon:

(i) the [**********] by Teva or its Affiliates (or its or their respective agents, contractors, Distributor/Commercial Partners, representatives or other Persons or working on its or their behalf) in the performance of this Agreement, the Development Supply Agreement, the Commercial Supply Agreement or either Quality Agreement, including in connection with its Development or Commercialization of the Product;

(ii) material breach by Teva (or conduct or omission by any of its Affiliates, or its or their respective agents, contractors, Distributor/Commercial Partners, representatives or other Persons working on its or their behalf, which if performed or failed to be performed by Teva would be a material breach by Teva or any of its Affiliates or its or their Distributor/Commercial Partners) of the terms of, or the representations and warranties made by it in, this Agreement; or

(iii) any Additional Trials undertaken by Teva under Section 5.4;

except in each case ((i), (ii) and (iii)), to the extent that Damages arise out of [**********] committed by Regeneron or its Affiliates (or their respective agents, contractors, representatives or other Persons working on their behalf) in the performance of this Agreement or the material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron) of the terms of this Agreement.

(b) Regeneron will defend, indemnify and hold harmless Teva, its Affiliates and its and their respective officers, directors, employees, Distributor/Commercial Partners and agents ("Teva Indemnitees") from and against all Damages arising from a Third Party Claim against a Teva Indemnitee that is due to or based upon:

(i) the [**********] by Regeneron or its Affiliates (or their respective agents, contractors, Distributor/Commercial Partners, representatives or

other Persons working on their behalf), in the performance of this Agreement, the Development Supply Agreement, the Commercial Supply Agreement or either Quality Agreement, including, in connection with the Development, Manufacture or Commercialization of the Product;

(ii) material breach by Regeneron (or conduct or omission by any of its Affiliates, or its or their respective agents, contractors, Distributor/Commercial Partners, representatives or other Persons working on its or their behalf, which if performed or failed to be performed by Regeneron would be a material breach by Regeneron or any of its Affiliates or its or their Distributor/Commercial Partners) of the terms of, or the representations and warranties made by it in, this Agreement, other than a material breach with respect to the Manufacture of the Product unless such material breach resulted from the [**********] by Regeneron or its Affiliates (or their respective agents, contractors, Distributor/Commercial Partners, representatives or other persons or entities working on their behalf);

(iii) the Commercialization of the Product outside of the Territory or the Development or Manufacture of Product in support thereof outside of this Agreement, in each case, by or on behalf of Regeneron, its Affiliates, or its or their Distributor/Commercial Partners (including Mitsubishi) other than Teva, its Affiliates or its or their Distributor/Commercial Partners; or

(iv) any Additional Trials undertaken by Regeneron under Section 5.4.

except in each case ((i), (ii), (iii), and (iv)), to the extent that Damages arise out of the [**********] committed by Teva or its Affiliates (or their respective agents, contractors, Distributor/Commercial Partners, representatives or other persons or entities working on their behalf) in the performance of this Agreement or the material breach by Teva (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Teva would be a material breach by Teva) of the terms of this Agreement.

(c) Mutual Indemnification.

(i) In the event of any Third Party Claim alleging that the Development, Manufacture or Commercialization of the Product under this Agreement infringes a Patent of a Third Party for which neither Party is entitled to indemnification hereunder or under an Ancillary Agreement, each Party shall indemnify the other Party for [**********] of all Damages therefrom and during the Term such Damages shall be [**********].

(ii) In the event of any product liability Third Party Claim alleging that the Development, Manufacture or Commercialization of the Product causes damages for which neither Party is entitled to indemnification hereunder or under an Ancillary Agreement, each Party shall indemnify the other for [**********] of all Damages therefrom and during the Term such Damages shall be [**********].

(d) During the Term and for a minimum period of [**********] thereafter and for an otherwise longer period as may be required by applicable Law, each of Regeneron and Teva will (i) use Commercially Reasonable Efforts to procure and maintain [**********] in an amount not less than [**********] per occurrence and in the annual aggregate or (ii) procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of similarly situated pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Teva, respectively, or any of their respective Affiliates or Distributor/Commercial Partners, due to injury, disability or death of any person or persons, or property damage arising from activities performed by such Party or its Affiliates or Distributor/Commercial Partners in connection with this Agreement. Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party under Section 17.1 with respect to such Damages.

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(e) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Teva Indemnitees, as the case may be) from Third Party Claims resulting from, and to the extent allocable to, the [**********]. In the event that Regeneron (or any of its Affiliates) obtains any recoveries from a Third Party manufacturer (at any time) with respect to Development Supply Requirements or Commercial Supply Requirements, (i) Regeneron shall be entitled to retain from such recoveries any amounts required to reimburse Regeneron (or its Affiliate) for any reasonable out-of-pocket expenses, including reasonable attorneys' fees, incurred in obtaining such recoveries and (ii) the remaining recoveries, if any, shall be shared by the Parties and their respective indemnified Persons in proportion to the Parties' (and their respective indemnified Persons') respective Third Party Claims.

17.2 Indemnity Procedure. The Party entitled to indemnification under this ARTICLE XVII (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within [**********] of being notified of any claim or claims asserted or threatened against the Indemnified Party that could give rise to a right of indemnification under this Agreement; *provided that* the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party. The indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for [**********] of all Damages under the terms of Section 17.1(c), and the Parties shall cooperate in good faith to establish a mutually agreeable strategy with respect to defending or prosecuting any Third Party Claims subject to Section 17.1(c). With respect to any Damages that are subject to Section 17.1(c), to the extent either Party or any of its Affiliates recovers any amounts with respect thereto from any Third Party pursuant to any agreement between such Party and such Third Party with respect to the activities that such Damages resulted from, such recoveries shall be shared equally by the Parties.

(a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending a claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; *provided that* the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld, conditioned or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least [**********] prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed); *provided that* the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

(b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; *provided that* the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.

(c) Regardless of whether the Indemnifying Party assumes the defense of any claim pursuant to this Section 17.2, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to, reasonably cooperate in the defense or prosecution thereof and, if the Indemnifying Party assumes the defense of any such claim, the Indemnified Party shall and shall use reasonable efforts to cause each indemnitee to furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals, in each case, as may be reasonably requested in connection therewith. Such cooperation shall include access upon reasonable notice during normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and to the extent the Indemnified Party is entitled to indemnification pursuant to this ARTICLE XVII, the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection with providing such assistance.

ARTICLE XVIII
FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance, and only if the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE XIX
TERM AND TERMINATION

19.1 Term/Expiration of Term.

(a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated in its entirety in accordance with the terms of this ARTICLE XIX, shall expire upon such time as neither Party nor any of its Affiliates or its or their Distributor/Commercial Partners is Developing the Product for, or Commercializing the Product in, the Field anywhere in the Territory under this Agreement (and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent).

(b) Upon expiration of the Term, all licenses and rights granted by a Party to the other Party hereunder shall automatically terminate and revert to the granting Party.

19.2 Termination For Material Breach.

(a) Termination for Material Breach. Upon and subject to the terms and conditions of this Section 19.2 and Section 10.3 and Section 19.4(b) (as applicable), this Agreement shall be terminable by a Party in its entirety, upon written notice to the other Party, if such other Party commits a material breach of its obligations under this Agreement, the Development Supply Agreement or the Commercial Supply Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination that is the subject of such notice shall be effective [**********] after the date such notice is given unless the breaching Party shall have cured such breach within such [**********] period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such [**********] period, such longer period not to exceed [**********] unless otherwise agreed by the Parties, so long as the breaching Party is using diligent efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such [**********] period or such time as the breaching party ceases to use diligent efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the [**********] period referred to in the immediately preceding sentence shall instead be [**********] (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). [**********]. For purposes of this Section 19.2, the term "material breach" shall mean [**********], taken as a whole.

Termination Disputes. No later than five (5) Business Days after delivery of a notice of termination by a Party pursuant to Section 19.2(a), the Executive Officers

of the Parties shall meet to discuss the breach that is the subject of such notice and the breaching Party's proposed plans to cure such breach. In the event that there is a dispute between the Parties as to whether a material breach has occurred or what efforts are required to cure the alleged material breach, and the breaching Party has determined reasonably and in good faith that it is not materially breaching the Agreement or that the efforts required to cure the breach are less than what the terminating Party believes are necessary (each a "Termination Dispute"), then such breaching Party shall provide the terminating Party with a written statement setting forth the basis for its determination and any facts and analysis in support thereof within five (5) Business Days after the meeting of the Executive Officers and the Executive Officers shall meet again within five (5) Business Days after delivery of such statement. If the Executive Officers are not able to resolve the Termination Dispute within five (5) Business Days after such second meeting, [**********].

19.3 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (b) the other Party proposes a written agreement of composition or extension of its debts, or (c) the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [**********] after the filing thereof, or (d) the other Party shall propose or become a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors. All rights and licenses granted under or pursuant to this Agreement by a Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar applicable Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101 (35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed under or pursuant to this Agreement, including, any Patents or Patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101 (35A) of the Bankruptcy Code subject to the protections afforded the non-rejecting Party under Section 365(n) of the Bankruptcy Code, and any similar applicable Law or regulation in any other country. The Parties agree that this Agreement shall not be deemed terminated by virtue of any rejection by a Party or its receiver or trustee under applicable bankruptcy applicable Laws unless the non-rejecting Party fails to exercise its rights under Section 365(n)(1)(B) of the U.S. Bankruptcy Code (or its foreign equivalents). For clarity, if the non-rejecting Party fails to exercise such rights or such rights are not available in a country outside the United States, this Agreement shall be deemed terminated. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous applicable Laws in any other country or jurisdiction, if this Agreement is not terminated or deemed terminated, the Party that is not the subject of such proceeding shall be

entitled to a complete duplicate of (or complete access to, as appropriate) all such licensed intellectual property and all embodiments of such intellectual property, which, if not already in such Party's possession, shall be promptly delivered to it upon such Party's written request, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement.

19.4 Additional Termination Rights of Regeneron.

(a) [**********].

(b) [**********].

(c) [**********].

(d) [**********].

19.5 Additional Termination Right of Teva. Teva shall have the right to terminate this Agreement in its entirety upon [**********] prior written notice to Regeneron. Except as otherwise noted in this Section 19.5, through the notice period set forth above (the "Termination Notice Period"), the Parties shall continue to Develop, Commercialize, and, with respect to Regeneron, Manufacture, the Product in the Field in the Territory in accordance with Plans and the terms of Schedule 4 shall apply. During the Termination Notice Period and as necessary thereafter, Teva shall, at Regeneron's request, [**********] transition to Regeneron, [**********], the continued Development and Commercialization of the Product in the Field in the Territory. In addition, during the Termination Notice Period, Regeneron shall have [**********].

19.6 Effect of Termination.

(a) Upon termination of this Agreement in its entirety for any reason, the provisions of Schedule 4 shall apply (including during any applicable Termination Notice Period) with respect to the Product, and except as set forth in this ARTICLE XIX or to the extent required by Teva to fulfill its obligations pursuant to Schedule 4, [**********].

(b) Upon termination of this Agreement in its entirety by Teva under Section 19.2, [**********].

(c) If Teva terminates this Agreement in its entirety under Section 19.5 after receipt of the first Marketing Approval of the Product in the European Union and [**********].

(d) [**********].

19.7 Survival of Obligations. Except as otherwise provided in this ARTICLE XIX, or Schedule 4, upon expiration, or upon termination of this Agreement, the rights and

obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect to the extent of such termination; *provided that* notwithstanding any expiration or termination of this Agreement:

(a) neither Teva nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be);

(b) subject to the provisions of this ARTICLE XIX, including Schedule 4 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and Product Information in accordance with ARTICLE XVI, as well as other provisions (including, ARTICLES XIV (with respect to costs incurred during the Term and for the period set forth therein), XVII, XVIII and XX and Sections 2.6(a)(ii) (only for the period set forth therein in the event of a termination under the sections identified therein), 2.6(c), 2.8 (only for the period set forth therein in the event of a termination under the sections identified therein), 4.1 (last sentence only), 4.2(a), 6.6(b), 6.8(e) (only upon expiration of this Agreement), 7.6 (only the last sentence with respect to Product sold during the Term), 7.7(a)(i) (with respect to Teva's obligations and Regeneron's rights), 7.7(c), 9.2 (only with respect to Development during the Term), 9.3 and 9.4 (only with respect to milestones achieved during the Term), 9.5 and 9.6 (only with respect to Net Sales of Product accrued during the Term) 9.9-9.19 (only for final post-term accounting), 10.3, 10.4, 10.5, 11.1, 11.3 (first and second sentences only), 11.5(b) (which grant shall become exclusive), 12.1, 12.2(c), 12.2(d) [**********], 12.2(e), 12.2(f) [**********], 12.3 (only with respect to Joint Patent Rights), 12.4(c) (third sentence only), 12.5, 12.6, 13.1 (only with respect to Joint Inventions and Joint Patent Rights), 13.3(f) (only the last sentence), 15.6, 15.9, 16.1, 16.2, 16.4, 19.3, 19.6, 19.7 and Schedules 2-3 (only for final post-term accounting), Schedule 4 and Schedule 6 (only for final post-term accounting)) that by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and

(c) such expiration or termination and this ARTICLE XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

ARTICLE XX
MISCELLANEOUS

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Except as set forth in ARTICLE X, each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of Delaware, and the United States District Court for the District of Delaware for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts. Each Party further agrees that service of any process, summons, notice or document delivered by reputable international overnight courier service to its address set forth in Section 20.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 5 attached hereto and shall be (a) delivered personally, or (b) sent via a reputable international overnight courier service. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand or one (1) Business Day after it is sent via a reputable international overnight courier service. Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement contains the complete understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating to the subject matter hereof (including the Confidentiality Agreement between Teva and Parent dated as of [**********] and amended by Amendment No. 1 as of [**********].

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Teva and Regeneron.

20.6 Severability.

(a) If, under applicable Laws, any provision hereof other than Section 9.6 is in violation of public policy or invalid, illegal, or unenforceable at law or in equity, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; *provided that* the Parties shall consult and use all reasonable efforts to agree upon, and hereby agree and consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

(b) [**********].

(c) [**********].

(d) For clarity, the court may not reform any provision of this Agreement without the consent of each Party.

20.7 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.8 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Teva or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Teva or (b) the prior written consent of Teva in the case of an assignment by Regeneron, except in each case (i) in whole or in part to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet a Party's obligations under this Agreement, as long as the assignee remains an Affiliate of the Parent with respect to Regeneron or the Controlling Parent for Teva as of the Effective Date with respect to Teva; *provided that* the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) in whole to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable

hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Teva Indemnitees to the extent provided in the last sentence of Section 20.12.

20.10 Affiliates. Each Party may, and to the extent it is in the best interests of the Product in the Field in the Territory shall, perform its obligations under this Agreement through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture (in the case of Regeneron) or Commercialization of the Product under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and that shall provide that the other Party is a third party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate.

20.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Agreement may be executed by exchange between the Parties of electronically transmitted signatures (via facsimile, PDF format via e-mail or other electronic means) and such signatures shall be deemed to bind each Party as if they were original signatures.

20.12 Third Party Beneficiaries. Except as provided below in this Section 20.12, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party. Notwithstanding the foregoing, ARTICLE XVII is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Teva Indemnitees as if they were parties hereto, but this Agreement is only enforceable by the Parties.

20.13 Relationship of the Parties. Each Party shall bear its own costs and expenses incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided for in this Agreement. Neither Teva nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Teva, and Teva's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.14 Limitation of Damages. IN NO EVENT SHALL REGENERON OR TEVA BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE (A) PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM THAT IS COVERED BY THE INDEMNIFICATION OBLIGATIONS IN ARTICLE XVII, OR (B) COVERED BY REGENERON'S INDEMNIFICATION OBLIGATION IN SECTION 2.6(C).

20.15 Standstill Agreement.

(a) During the period commencing on the Effective Date and expiring on the date that is five (5) years after the end of the Term (such period, as it may earlier terminate pursuant to Section 20.15(b), the "Standstill Term"), neither Teva nor any of its Affiliates shall (and Teva shall cause such Affiliates not to), except as expressly invited in writing by Parent (for purposes of this Section 20.15, Teva, together with such Affiliates, being referred to, collectively, as the "Investor"):

(i) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock or any securities convertible into or exchangeable for Shares of Then Outstanding Capital Stock, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock, if after giving effect to such acquisition, the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended, or any successor thereto) five percent (5%) or more of the Shares of Then Outstanding Capital Stock; *provided*,

however, that notwithstanding the provisions of this Section 20.15, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if the aggregate ownership of the Investor is increased as a result of a recapitalization of Parent, Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted in the Investor's ownership totaling five percent (5%) or more of the Shares of Then Outstanding Capital Stock immediately after the completion of such recapitalization;

(ii) directly or indirectly, seek to have called any meeting of the shareholders of Parent, propose or nominate for election to the Board of Directors of Parent (the "Board") any Person whose nomination has not been approved by a majority of the Board, or vote or cause to be voted in favor of such Person for election to the Board any Shares of Then Outstanding Capital Stock;

(iii) directly or indirectly, knowingly encourage, accept or support a tender, exchange or other offer or proposal by any other Person or group (each, an "Offeror") the consummation of which would result in a Change of Control of Parent; *provided*, *however*, that from and after the filing of a Schedule 14D-9 (or successor form of Tender Offer Solicitation/Recommendation Statement under Rule 14d-9 of the Exchange Act) by Parent recommending that shareholders accept any such offer filed after such offer has commenced, Investor shall not be prohibited from taking any of the actions otherwise prohibited by this clause (iii) for so long as Parent maintains and does not withdraw such recommendation;

(iv) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Securities Exchange Act of 1934, as amended, or any successor thereto) in opposition to the recommendation of a majority of the Board with respect to any matter, or seek to advise or knowingly influence any Person, with respect to voting of any Shares of Then Outstanding Capital Stock of Parent;

(v) deposit any Shares of Then Outstanding Capital Stock in a voting trust or subject any Shares of Then Outstanding Capital Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Capital Stock;

(vi) act in concert with any Third Party to take any action in clauses (i) through (v) above, or form, join or in any way participate in a partnership, limited partnership, syndicate or other group within the meaning of Section 13(d)(3) of the Securities Act of 1934, as amended, or any successor thereto;

(vii) request or propose that Parent or any of Parent's officers or the Board (or any committee thereof) amend, waive, or consider the amendment or waiver of any provisions set forth in this Section 20.15; or

(viii) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in clauses (i) through (vii) above;

provided that (A) nothing contained in this Section 20.15 shall prohibit the Investor or its Affiliates from making confidential, non-public proposals to, or entering into confidential, non-public discussions, negotiations, arrangements or agreements with, Parent and with the express, prior authorization of Parent provided to the Investor in writing, with Third Parties, that the Investor or such Affiliate may request in a confidential, non-public manner, regarding a transaction or matter of the type described in the foregoing clause (i), and (B) the mere voting of any Shares of Then Outstanding Capital Stock held by the Investor shall not constitute a violation of any of clauses (i) through (vi) above.

(b) Termination of Standstill. Provided the Investor has not violated Section 20.15(a)(iii), (iv), (vi) or (viii) with respect to the Offeror referred to in this Section 20.15(b), the restrictions contained in Section 20.15(a) shall terminate upon the earlier to occur of:

(i) the public announcement by Parent recommending acceptance by Parent's shareholders of a tender offer or exchange offer by an Offeror that, if consummated, would constitute a Change of Control of Parent;

(ii) the public announcement by Parent or an Offeror of any definitive agreement providing for a Change of Control of Parent;

(iii) the acquisition by an Offeror of beneficial ownership of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by the Offeror, represents more than thirty percent (30%) of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock;

(iv) the issuance by Parent to a Third Party (other than an underwriter in a public offering that promptly distributes such shares to the public) of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by such Third Party immediately prior to such issuance, represents more than ten percent (10%) of the voting power represented by all issued and outstanding Shares of Then Outstanding

Capital Stock immediately after giving effect to such issuance, if Parent does not enter into a standstill agreement with such Third Party upon material terms substantially similar to the provisions of Section 20.15(a);

(v) a sale of all or substantially all of the assets of Parent (other than to a wholly owned Affiliate of Parent); or

(vi) a liquidation or dissolution of Parent that would give rise to a termination of this Agreement pursuant to Section 19.3;

provided, *however*, that if any of the transactions referred to in (i), (ii), (iii) or (v) above terminates and Parent has not made a public announcement of its intent to solicit or engage in a transaction referred to in Section 20.15(a) (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of Parent, then the restrictions contained in Section 20.15(a) shall again be applicable.

In addition, for the avoidance of doubt and subject to the preceding sentence, from and after the expiration or termination of the Standstill Term, no provision of this Agreement or any of the related agreements shall restrict the Investor or its Affiliates, directly or indirectly, from taking any actions or engaging in activities described in clauses (i) through (viii) of Section 20.15(a).

20.16 Construction.

(a) The use of words in the singular or plural, or with a particular gender, shall not limit the scope or exclude the application of any provision of this Agreement to such person or persons or circumstances as the context otherwise permits. The words “will” and “shall” shall have the same meaning and, unless the context otherwise requires, the use of the word “or” is used in the inclusive sense (and/or). The term “including,” “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term, irrespective of whether such term is used with “without limitation” or “without limiting” throughout this Agreement. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. [**********].

(b) The captions of this Agreement are for convenience or reference only and in no way define, describe, extend or limit the scope of intent of this Agreement or in the intent of any provision contained in this Agreement. Unless otherwise specified, (i) the references in this Agreement to any Article, Section, Exhibit, Schedule or Appendix means references to such Article, Section, Exhibit, Schedule or Appendix of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section and (iii) unless the context otherwise

requires, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

(c) Whenever a provision of this Agreement requires an approval or consent by a Party to this Agreement within a specified time period and notification of such approval or consent is not delivered within such time period, then, unless otherwise specified, the Party whose approval or consent is required shall be conclusively deemed to have withheld its approval or consent. This Agreement has been prepared jointly and the provisions contained herein shall not be construed or interpreted for or against any Party to this Agreement because such Party drafted or caused such Party's legal representative to draft any provision contained herein.

(d) In the event of any conflict between this Agreement and the Schedules, Exhibits or Appendices hereto, this Agreement shall prevail.

20.17 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Teva and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Teva Pharmaceuticals International GmbH

By: /s/ Naama Baram

Name: Naama Baram

Title: General Manager

By: /s/ R. David Koch

Name: David Koch

Title:Managing Officer

Regeneron Ireland

By: /s/ Jeffrey Landry

Name: Jeffrey Landry

Title: Director

SCHEDULE 1

Initial Global Development Plan

[**********]

SCHEDULE 1.57

Existing Agreements

[**********]

SCHEDULE 1.142

Regeneron Product Patent Rights

[**********]

SCHEDULE 2

Manufacturing Cost

"Manufacturing Cost" as used in this Agreement [**********] shall be determined as provided in this Schedule 2 [**********].

A. General Principles

1. The costs of Finished Product supplied by Regeneron for Development Supply Requirements or Commercial Supply Requirements shall be [**********].

2. To the extent Regeneron uses Finished Product (including Formulated Bulk Product contained therein) that was Manufactured by Regeneron prior to the Effective Date, the costs of such Formulated Bulk Product or Finished Product shall be[**********].

3. [**********].

4. Manufacturing Cost shall be calculated using methodology that is in accordance with Regeneron's Accounting Standards at the election of Regeneron and consistently applied by Regeneron throughout its operations, without any mark-up. [**********].

5. [**********].

6. [**********].

B. Fully Burdened Manufacturing Cost

1. "Fully Burdened Manufacturing Cost" includes the following costs of preparations for, and the Manufacture of, Finished Product (including Formulated Bulk Product contained therein) [**********].

(a) Direct Costs incurred by Regeneron:

(i) [**********].

(ii) [**********].

(iii) [**********].

(iv) [**********].

(b) Indirect Costs incurred by Regeneron:

(i) [**********].

(ii) [**********].

(c) [**********].

[**********].

C. [**********]

[**********].

SCHEDULE 3

Quarterly True-Up

[**********]:

[**********]

SCHEDULE 4

Certain Termination Arrangements

1. (a) Teva shall promptly collect and return, and cause its Affiliates and Distributor/Commercial Partners and subcontractors to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing Product Information or Party Information of Regeneron or any of its Affiliates or its or their Distributor/Commercial Partners or subcontractors, except to the extent that such Party Information is necessary for Teva or any of its Affiliates and its and their designees to exercise their surviving rights under this Agreement, and shall immediately cease, and cause its Affiliates and its and their Distributor/Commercial Partners and subcontractors to cease, all further use of any such Product Information and Party Information. [**********]. Notwithstanding the foregoing, (i) Teva may retain copies of any Party Information or Product Information to the extent required by applicable Law, as well as retain one (1) copy of such information solely for legal archive purposes and (ii) any such Party Information or Product Information covered by an exclusion set forth in Section 16.1(b) shall not be subject to the foregoing obligations; *provided that* such copies referenced in clause (i) will continue to be subject to the terms and conditions of this Agreement, including, obligations of confidentiality and non-use/non-disclosure in accordance herewith. (b) Regeneron shall promptly collect and return, and cause its Affiliates and its and their Distributor/Commercial Partners and subcontractors to collect and return, to Teva or, at Teva's request, destroy, all documents containing Party Information of Teva or any of its Affiliates or its or their Distributor/Commercial Partners or subcontractors, except to the extent that such Party Information is necessary for Regeneron or any of its Affiliates and its and their nominees or designees to exercise their surviving rights under this Agreement, and shall immediately cease, and cause its Affiliates and its and their Distributor/Commercial Partners and subcontractors to cease, all further use of any such Party Information. Notwithstanding the foregoing, (i) Regeneron may retain copies of any such Party Information to the extent required by applicable Law, as well as retain one (1) copy of such information solely for legal archive purposes and (ii) any such Party Information covered by an exclusion set forth in Section 16.1(b) shall not be subject to the foregoing obligations; *provided that* such copies referenced in clause (i) will continue to be subject to the terms and conditions of this Agreement, including, obligations of confidentiality and non-use/non-disclosure in accordance herewith.

2. [**********].

3. [**********]:

(a) Teva shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other Approvals and regulatory filings (including Registration Filings) made or obtained by Teva or its Affiliates or any of its Distributor/Commercial Partners in performance of this Agreement to the extent specifically relating to the Product; [**********].

(b) To the extent permitted by applicable Law or the applicable Regulatory Authority, transition and transfer control to Regeneron of all clinical trials being

conducted under this Agreement by Teva with respect to the Product as of the effective date of termination to enable such transfer to be completed in accordance therewith [**********].

(c) Teva shall assign and transfer to Regeneron (or its nominee or designee) Teva's entire right, title and interest in and to any Product Trademarks for the Product and Promotional Materials relating to the Product; *provided that* nothing herein is intended to convey any rights in or to Teva's corporate name and logos or any trade names except for the limited rights set forth herein.

(d) Teva shall provide to Regeneron (or its nominee or designee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Product in the Field for the Territory) of all information (including any Product Information and Product Inventions) in Teva's possession and control, or in Teva's control and accessible by Teva consistent with Teva's regular business practices, to the extent directly relating to the Product in the Field, including, all such information contained in the regulatory or safety databases maintained by either Party hereunder, all in the format then currently maintained by Teva, or such other format as may be reasonably requested by Regeneron.

(e) Teva shall [**********] assign to Regeneron any applicable Licenses and sublicenses specific and solely attributable to the Product and other material service provider contracts for significant services to be performed by Third Parties specific and solely attributable to the Development, or Commercialization of the Product in the Field for the Territory, as reasonably requested by Regeneron. [**********].

4. Without limitation of the generality of the foregoing, the Parties shall [**********] complete the transition of the Development and Commercialization of the Product in the Field hereunder to Regeneron (or its sublicensee or Third Party nominee or designee) as soon as is reasonably possible.

5. For the avoidance of doubt, except as expressly provided in this Agreement, including Section 19.6(b) (if applicable), Regeneron shall not be required to provide Teva any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 4; *provided that* Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Teva may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

6. Without limitation of any of the foregoing in this Schedule 4, Teva shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as Regeneron may reasonably request in connection with, or to carry out more effectively the purpose of, or to better assure and confirm unto Regeneron its rights under Section 19.6 and this Schedule 4.

7. All costs and expenses incurred by Teva with respect to the activities under this Schedule 4 shall be [**********].

SCHEDULE 5

Notices

(a) If to Teva:

Teva Pharmaceuticals International GmbH
Schlüsselstrasse 12
8645 Jona
Switzerland
Attn: Naama Baram, General Manager

With a copy (which shall not constitute notice) to:
Teva Pharmaceuticals
425 Privet Road
Horsham, PA 19044
Attn: General Counsel

(b) If to Regeneron:

Regeneron Ireland
Europa House

Harcourt Street
Dublin 2, Ireland
Attention: General Manager

Copy to:

Regeneron Pharmaceuticals, Inc.

777 Old Saw Mill River Road

Tarrytown, New York, 10599

Attention: Corporate Secretary

SCHEDULE 6

[**********]

[**********]	[**********]
[**********]	[**********]
[**********]	[**********]

[**********]

SCHEDULE 7.7

[**********]

[**********]

SCHEDULE 8.3

DEVELOPMENT SUPPLY TERMS

TERM SHEET FOR CLINICAL SUPPLY AGREEMENT

The Clinical Supply Agreement between Regeneron and Teva to be entered into pursuant to the definitive collaboration agreement between Regeneron and Teva (the "Collaboration Agreement"), shall include the following terms:

Scope	Regeneron will use Commercially Reasonable Efforts to manufacture (or have manufactured) and supply (or have supplied) to Teva, filled/finished Product for Development in the Ex-U.S. Territory, as further specified in the Collaboration Agreement.
Packaging/Labeling	Teva will be responsible for providing all Ex-U.S. Territory-specific labeling instructions and package insert text.
Purchase Price	Governed by Collaboration Agreement
Incoterm	Delivery at Place (ex-U.S. to be determined)
Forecasting/Orders	[**********]
Deviating Product	If deviating Product is delivered to Teva, Regeneron will, as soon as commercially practical, replace the Product with conforming Product, such replacement to be at Regeneron's cost provided such deviation results from [**********]. Regeneron will bear the cost of any replacement Product and the transportation, testing and disposal costs of any deviating Product, to the extent provided above. If deviating Product does not result from [**********], then the costs described in this Section will be borne as provided in the Collaboration Agreement.
Variances	If Teva fails to meet its firm order commitment, then Regeneron will use reasonable efforts to reallocate the excess Product. If Regeneron cannot re-allocate any such Product, then Teva will be obligated to purchase such Product. If Teva's orders exceed the Firm Order forecast, then Regeneron will use reasonable efforts to meet those orders, but will not be liable if it is not able to do so.
Warranties	[**********]
Maintenance of Facilities	Governed by Quality Agreement
Retention of Records	Regeneron will retain quality and production records for such time period as required by law and will provide such records to Teva upon request.
Recalls	Governed by the Collaboration Agreement
Audit Rights	Governed by the Collaboration Agreement
Indemnification	Governed by the Collaboration Agreement
Termination	Governed by the Collaboration Agreement
Confidentiality	Governed by the Collaboration Agreement

SCHEDULE 13.3

[**********]

[**********]

SCHEDULE 13.3(c)(ii)

[**********]

[**********]

SCHEDULE 15.4

REPRESENTATIONS AND WARRANTIES

None

SCHEDULE 15.4(j)

DISCLOSURE OF CERTAIN AGREEMENTS

[**********]

[**********]

SCHEDULE 15.4(l)

[**********]

[**********]

EXHIBIT A

Quarterly Inventory Report and Annual Inventory Report

[**********]

EXHIBIT B

Purchase Price Adjustment Calculation

[**********]

EXHIBIT C

FTE Rates

	[**********]	[**********]
[**********]	[**********]	[**********]
[**********]	[**********]	[**********]
[**********]	[**********]	[**********]

[**********]

EXHIBIT D

Press Release

Press Release | for immediate release

REGENERON

Teva and Regeneron Announce Global Collaboration to Develop and Commercialize Fasinumab, an Investigational NGF Antibody for Chronic Pain

Novel Nerve Growth Factor (NGF) Antibody Has Potential to Address Limitations of Current Non-Steroidal Anti-Inflammatory Drug (NSAID) and Opioid Therapies

Jerusalem and Tarrytown, NY, September 20, 2016 – Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) and Regeneron Pharmaceuticals, Inc (NASDAQ: REGN) announced today a global[1] agreement to develop and commercialize fasinumab, Regeneron's investigational NGF antibody in Phase 3 clinical development for osteoarthritis pain and in Phase 2 development for chronic low back pain. Under the terms of the agreement, Teva will pay Regeneron $250 million upfront and share equally in the ongoing research and development costs.

"Adding the promise of fasinumab to our developing pipeline of pain products provides a strong, strategic cornerstone to our program at Teva. In the United States alone, it is estimated that 40 million people suffer pain from osteoarthritis and chronic low back pain. This product has the potential to provide a novel treatment option for many of them," said Rob Koremans, MD., President and CEO of Global Specialty Medicines for Teva. "This is a significant transaction for Teva and with our commercial footprint, we will be able to widely educate healthcare providers about the option when it becomes available."

Under the terms of the agreement, Regeneron is eligible to receive development and regulatory milestones and additional payments based on net sales. The companies will split profit equally in the United States. Outside the U.S., Regeneron will supply the product at a range of purchase prices depending on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron will lead global development and U.S. commercialization, while Teva will lead ex-U.S. development and commercialization.

"Millions of people worldwide live with osteoarthritis pain and have inadequate pain relief or abuse and

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[1] *Under a previously announced collaboration agreement with Regeneron, Mitsubishi Tanabe Pharma has exclusive development and commercial rights to fasinumab in Japan, Korea and nine other Asian countries, excluding China.*

Teva IR Contacts:	**Kevin C. Mannix**	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
Regeneron IR Contact:	**Manisha Narasimhan, PhD**	United States	(914) 847-5126
	manisha.narasimhan@regeneron.com		
Teva PR Contacts:	**Iris Beck Codner**	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974
	Nancy Leone	United States	(215) 284-0213
Regeneron PR Contact:	**Hala Mirza**	United States	(914) 847-3422
	hala.mirza@regeneron.com		

tolerability concerns with current NSAID and opioid treatment options," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer, Regeneron and President, Regeneron Laboratories. "The development of novel pain medicines without abuse potential, such as fasinumab, can be one important step in combating the growing opioid epidemic. Fasinumab represents the culmination of more than 25 years of Regeneron scientific work in neurotrophic factors. We look forward to working with Teva, a leader in pain therapeutics, to rapidly advance this program for patients in need."

Fasinumab is a fully human monoclonal antibody that targets NGF, a protein that plays a central role in the regulation of pain signaling. There is evidence that NGF levels are elevated in patients with chronic pain conditions. Fasinumab is currently being studied in a global Phase 3 program for OA pain and one is planned for chronic low back pain (CLBP).

Under a previously announced collaboration agreement with Regeneron, Mitsubishi Tanabe Pharma has exclusive development and commercial rights to fasinumab in Japan, Korea and nine other Asian countries, excluding China.

About Chronic Osteoarthritis and Chronic Low Back Pain

In the U.S. more than 20 million people live with OA pain[2] with a similar number for CLBP[3], both of which are expected to grow in the low-single digit percentages annually.[1,2] Many patients experience pain at moderate-to-severe levels with intolerance[4] and/or inadequate response[5] to current analgesic therapies such as opioids and NSAIDs. There is a great need for highly effective analgesics medications to provide patients relief without the toxicity and tolerability challenges of NSAIDs and opioids.[3] Opioid prescriptions account for 40% of the chronic pain market[6] and carry a well-known risk of abuse and misuse[3], underscoring the need for alternative pain therapies without the medical and societal challenges.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,800 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2015 amounted to $19.7 billion. For more information, visit www.tevapharm.com.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL-cholesterol and a rare inflammatory condition and has product candidates in development in other

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[2] Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 120
3 Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 115
4 Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 148-149
5 Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 147
6 Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 7

areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products; competition for our specialty products, especially Copaxone® (which faces competition from orally-administered alternatives and a generic version); our ability to integrate Allergan plc's worldwide generic pharmaceuticals business ("Actavis Generics") and to realize the anticipated benefits of the acquisition (and the timing of realizing such benefits); the fact that following the consummation of the Actavis Generics acquisition, we are dependent to a much larger extent than previously on our generic pharmaceutical business; potential restrictions on our ability to engage in additional transactions or incur additional indebtedness as a result of the substantial amount of debt incurred to finance the Actavis Generics acquisition; the fact that for a period of time following the Actavis Generics acquisition, we will have significantly less cash on hand than previously, which could adversely affect our ability to grow; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from investments in our pipeline of specialty and other products; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and

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payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2015 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statements or other information, whether as a result of new information, future events or otherwise.

Regeneron Forward-Looking Statements and Use of Digital Media

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation fasinumab (REGN475) and the collaboration agreement with Teva Pharmaceutical Industries Ltd. discussed in this news release; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators (including without limitation the development of fasinumab conducted pursuant to the collaboration agreement discussed in this news release) may lead to therapeutic applications; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates, including without limitation fasinumab for pain due to osteoarthritis and chronic low back pain and other potential indications; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials, such as the current and contemplated global clinical development programs evaluating fasinumab; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates (such as fasinumab) and new indications for marketed products; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC (or their respective affiliated companies, as applicable) and the collaboration agreement with Teva Pharmaceutical Industries Ltd. discussed in this news release, to be cancelled or terminated without any product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2015 and its Form 10-Q for the quarterly period ended June 30, 2016. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any

obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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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 4, 2016

/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 4, 2016

/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, 2016 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 4, 2016

/s/ Robert E. Landry

Robert E. Landry

Senior Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

November 4, 2016