REGENERON PHARMACEUTICALS INC
Form 10-Q
May 05, 2016

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 March 31, 2016

OR

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

Commission File Number 0-19034
REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York	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 April 14, 2016:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,913,136
Common Stock, $.001 par value	103,165,457

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

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$604,214	$809,102
Marketable securities	244,965	236,121
Accounts receivable - trade, net	1,450,572	1,152,489
Accounts receivable from Sanofi	173,782	153,152
Accounts receivable from Bayer	240,867	162,152
Inventories	303,294	238,578
Prepaid expenses and other current assets	115,685	163,501
Total current assets	3,133,379	2,915,095
Marketable securities	555,210	632,162
Property, plant, and equipment, net	1,666,391	1,594,120
Deferred tax assets	543,689	461,945
Other assets	5,791	5,810
Total assets	$5,904,460	$5,609,132
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$733,276	$644,112
Deferred revenue from Sanofi, current portion	99,314	101,573
Deferred revenue - other, current portion	73,626	51,914
Other current liabilities	13,508	13,563
Total current liabilities	919,724	811,162
Deferred revenue from Sanofi	565,773	582,664
Deferred revenue - other	170,658	82,015
Facility lease obligations	362,230	362,919
Other long-term liabilities	120,993	115,535
Total liabilities	2,139,378	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 - 1,913,136 in 2016 and 1,913,776 in 2015	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 106,739,966 in 2016 and 106,378,001 in 2015	107	106
Additional paid-in capital	3,049,651	3,099,526
Retained earnings	1,018,436	852,700

Accumulated other comprehensive income	4,364	8,572
Treasury stock, at cost; 3,659,588 shares in 2016 and 3,642,820 in 2015	(307,478)	(306,069)
Total stockholders' equity	3,765,082	3,654,837
Total liabilities and stockholders' equity	$5,904,460	$5,609,132

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

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

	Three Months Ended March 31,	
	2016	2015
Statements of Operations		
Revenues:		
Net product sales	$784,182	$544,573
Sanofi collaboration revenue	219,694	173,356
Bayer collaboration revenue	179,592	123,846
Other revenue	17,381	27,837
	1,200,849	869,612
Expenses:		
Research and development	470,112	343,113
Selling, general, and administrative	289,677	158,991
Cost of goods sold	78,942	42,570
Cost of collaboration and contract manufacturing	32,810	41,385
	871,541	586,059
Income from operations	329,308	283,553
Other income (expense):		
Investment income	2,249	180
Interest and other expense, net	(1,406)	(7,210)
	843	(7,030)
Income before income taxes	330,151	276,523
Income tax expense	(164,415)	(200,502)
Net income	$165,736	$76,021
Net income per share - basic	$1.59	$0.74
Net income per share - diluted	$1.45	$0.66
Weighted average shares outstanding - basic	104,290	102,227
Weighted average shares outstanding - diluted	114,228	114,519
Statements of Comprehensive Income		
Net income	$165,736	$76,021
Other comprehensive income (loss):		
Unrealized loss on marketable securities, net of tax	(4,208)	(4,347)
Comprehensive income	$161,528	$71,674

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

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

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net income	$165,736	$76,021
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	22,977	16,027
Non-cash compensation expense	142,250	103,759
Other non-cash charges and expenses, net	3,957	8,808
Deferred taxes	(79,785)	(37,256)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer, and trade accounts receivable	(397,428)	(329,746)
Increase in inventories	(62,263)	(5,434)
Decrease in prepaid expenses and other assets	39,260	43,434
Increase (decrease) in deferred revenue	91,205	(7,457)
Increase in accounts payable, accrued expenses, and other liabilities	103,431	30,117
Total adjustments	(136,396)	(177,748)
Net cash provided by (used in) operating activities	29,340	(101,727)
Cash flows from investing activities:		
Purchases of marketable securities	—	(95,775)
Sales or maturities of marketable securities	60,409	80,456
Capital expenditures	(104,094)	(114,162)
Net cash used in investing activities	(43,685)	(129,481)
Cash flows from financing activities:		
(Payments) proceeds in connection with facility lease obligations	(598)	6,738
Repayments of convertible senior notes	(1,739)	(16,686)
Payments in connection with reduction of outstanding warrants	(242,117)	(124,531)
Proceeds from issuance of Common Stock	39,304	76,273
Payments in connection with Common Stock tendered for employee tax obligations	(1,042)	(21,192)
Excess tax benefit from stock-based compensation	15,649	169,794
Net cash (used in) provided by financing activities	(190,543)	90,396
Net decrease in cash and cash equivalents	(204,888)	(140,812)
Cash and cash equivalents at beginning of period	809,102	648,719
Cash and cash equivalents at end of period	$604,214	$507,907

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

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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 $780.9 million and $541.1 million for the three months ended March 31, 2016 and 2015, respectively. In addition, ARCALYST® net product sales totaled $3.3 million and $3.5 million for the three months ended March 31, 2016 and 2015, respectively.

For the three months ended March 31, 2016 and 2015, the Company recorded 60% and 69%, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the three months ended March 31, 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	18,885	35,788	2,910	57,583
Credits/payments	(17,457)	(50,353)	(2,557)	(70,367)
Balance as of March 31, 2016	$ 7,847	$ 33,748	$ 870	$42,465
Balance as of December 31, 2014	$ 3,083	$ 21,166	$ 532	$24,781
Provision related to current period sales	11,353	24,781	1,383	37,517
Credits/payments	(9,779)	(13,036)	(1,411)	(24,226)
Balance as of March 31, 2015	$ 4,657	$ 32,911	$ 504	$38,072

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REGENERON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
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3. Collaboration Agreements

a. Sanofi

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

	Three Months Ended March 31,	
Sanofi Collaboration Revenue	2016	2015
Antibody:		
Reimbursement of Regeneron research and development expenses	$193,602	$168,820
Reimbursement of Regeneron commercialization-related expenses	73,274	8,458
Regeneron's share of losses in connection with commercialization of antibodies	(99,422)	(22,405)
Other	2,965	2,561
Total Antibody	170,419	157,434
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	29,275	—
Other	20,000	—
Total Immuno-oncology	49,275	—
ZALTRAP®:		
Reimbursement of Regeneron research and development expenses	—	686
Other	—	15,236
Total ZALTRAP	—	15,922
	$219,694	$173,356

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 will fund up to $130.0 million of the Company's research activities in each of 2016 and 2017. Under the License and Collaboration Agreement, agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. During the three months ended March 31, 2016 and 2015, the Company recognized as additional research and development expense $21.7 million and $25.0 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, dupilumab.

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

During the three months ended March 31, 2015, the Company and Sanofi shared pre-launch commercialization expenses, including those incurred by Sanofi, related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In addition, effective in the first quarter of 2016, the Company and Sanofi also began sharing pre-launch commercialization expenses related to dupilumab. As such, the Company recorded its share of losses in connection with preparing to commercialize Praluent, sarilumab, and dupilumab within Sanofi collaboration revenue. In July 2015, the U.S. Food and Drug

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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.

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 first quarter of 2015, the Company recorded $19.8 million, in other revenue, primarily related to manufacturing ZALTRAP commercial supplies for Sanofi, and a percentage of net sales of ZALTRAP from July 1, 2014 (the effective date of the Amended ZALTRAP Agreement) through March 31, 2015. During the first quarter of 2016, the Company recorded $5.3 million, in other revenue, primarily related to a percentage of net sales of ZALTRAP and manufacturing ZALTRAP commercial supplies for Sanofi.

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

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

	Three Months Ended March 31,	
Bayer Collaboration Revenue	2016	2015
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$145,835	$89,426
Sales milestones	—	15,000
Cost-sharing of Regeneron EYLEA development expenses	2,743	2,657
Other	26,492	12,912
Total EYLEA	175,070	119,995
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept (REGN2176-3) development expenses	1,896	1,254
Other	2,626	2,597
Total PDGFR-beta	4,522	3,851
	$179,592	$123,846

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
On March 23, 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 was obligated to make a $50.0 million non-refundable up-front payment to the Company (which was receivable as of March 31, 2016) 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

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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. Intellia Therapeutics

In April 2016, the Company entered into a license and collaboration agreement with Intellia Therapeutics, Inc., a privately held company, 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 in April 2016, and has also agreed to purchase up to $50.0 million of 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 one-time 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.

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(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 March 31,	
	2016	2015
Net income - basic	$165,736	$76,021
Effect of dilutive securities:		
Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs	56	—
Net income - diluted	$165,792	$76,021
(Shares in thousands)		
Weighted average shares - basic	104,290	102,227
Effect of dilutive securities:		
Stock options	8,147	9,313
Restricted stock	469	467
Convertible senior notes	44	—
Warrants	1,278	2,512
Dilutive potential shares	9,938	12,292
Weighted average shares - diluted	114,228	114,519
Net income per share - basic	$1.59	$0.74
Net income per share - diluted	$1.45	$0.66

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

	Three Months Ended March 31,	
(Shares in thousands)	2016	2015
Stock options	7,539	3,673
Restricted stock	19	—
Convertible senior notes	—	1,929

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

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

As of March 31, 2016	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate bonds	$710,989	$1,920	$(879)	$712,030
U.S. government and government agency obligations	50,383	194	(2)	50,575
Municipal bonds	16,113	45	(3)	16,155
Equity securities	17,005	10,057	(5,647)	21,415
	$794,490	$12,216	$(6,531)	$800,175

As of December 31, 2015				
Corporate bonds	$770,092	$156	$(2,565)	$767,683
U.S. government and government agency obligations	51,402	—	(193)	51,209
Municipal bonds	17,930	5	(11)	17,924
Equity securities	17,005	14,461	—	31,466
	$856,429	$14,622	$(2,769)	$868,282

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of March 31, 2016 mature at various dates through August 2020. The fair values of debt security investments by contractual maturity consist of the following:

	March 31, 2016	December 31, 2015
Maturities within one year	$244,965	$236,121
Maturities after one year through five years	533,795	600,695
	$778,760	$836,816

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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 March 31, 2016	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$132,085	$ (190)	$135,211	$ (689)	$267,296	$ (879)
U.S. government and government agency obligations	7,822	(3)	—	—	7,822	(3)
Municipal bonds	2,571	(2)	—	—	2,571	(2)
Equity securities	9,353	(5,647)	—	—	9,353	(5,647)
	$151,831	$ (5,842)	$135,211	$ (689)	$287,042	$ (6,531)
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)

There were no realized gains and losses on sales of marketable securities for the three months ended March 31, 2016, and such amounts were not material for the three months ended March 31, 2015.

Changes in the Company's accumulated other comprehensive income (loss) for the three months ended March 31, 2016 and 2015 related to unrealized gains and losses on available-for-sale marketable securities. For the three months ended March 31, 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; there were no such amounts reclassified during the three months ended March 31, 2016.

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6. Fair Value Measurements

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

As of March 31, 2016	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Available-for-sale marketable securities:			
Corporate bonds	$712,030	—	$712,030
U.S. government and government agency obligations	50,575	—	50,575
Municipal bonds	16,155	—	16,155
Equity securities	21,415	$21,415	—
	$800,175	$21,415	$778,760
As of December 31, 2015			
Available-for-sale marketable securities:			
Corporate bonds	$767,683	—	$767,683
U.S. government and government agency obligations	51,209	—	51,209
Municipal bonds	17,924	—	17,924
Equity securities	31,466	$31,466	—
	$868,282	$31,466	$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 months ended March 31, 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 months ended March 31, 2016 and 2015. During the three months ended March 31, 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 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 three months ended March 31, 2016 and 2015.

As of March 31, 2016 and December 31, 2015, the Company had $10.6 million and $11.2 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") outstanding that will mature on October 1, 2016 unless earlier converted or repurchased (see Note 9). The fair value of the outstanding Notes was estimated to be $49.6 million and $72.8 million as of March 31, 2016 and December 31, 2015, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

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7. Inventories

Inventories consist of the following:

	March 31, 2016	December 31, 2015
Raw materials	$85,180	$59,151
Work-in-process	157,921	132,068
Finished goods	14,231	11,197
Deferred costs	45,962	36,162
	$303,294	$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 March 31, 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $4.3 million and $1.7 million, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2016	December 31, 2015
Accounts payable	$120,595	$140,962
Accrued payroll and related costs	92,668	133,223
Accrued clinical trial expense	82,533	88,297
Accrued sales-related charges, deductions, and royalties	190,763	195,986
Income taxes payable	144,078	—
Other accrued expenses and liabilities	102,639	85,644
	$733,276	$644,112

9. Debt

a. Convertible Debt

In the first quarter of 2016, the Company settled conversion obligations for $1.7 million principal amount of the Company's Notes that was previously surrendered for conversion. Consequently, in the first quarter of 2016, the Company paid $1.7 million in cash and issued 16,774 shares of Common Stock. In addition, the Company allocated $6.7 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholder's equity. The loss on the debt extinguishment in connection with the Notes that were surrendered for conversion during the first quarter of 2016 was not material.

As a result of these Note conversions, in the first quarter of 2016, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 16,768 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 $1.4 million, as Treasury Stock during the first quarter of 2016.

As of March 31, 2016, an aggregate principal amount of $10.6 million of Notes remained outstanding. In addition to the Note conversions described above, the Company received notifications in April 2016 that an additional $10.4 million aggregate principal amount of the Notes was surrendered for conversion, and settlement is anticipated during the second quarter of 2016. The Company has elected to settle the related conversion obligations through a combination of cash and shares (total payment will be based on

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the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, the Company exercised a proportionate amount of its convertible note hedges, for which the Company expects to receive shares of Common Stock approximately equal to the number of shares the Company will be required to issue to settle the non-cash portion of the related Note conversions.

In the first quarter of 2015, the Company settled conversion obligations for $16.7 million principal amount of the Company's Notes. Upon settlement of the Notes, the Company paid $16.7 million in cash and issued 146,253 shares of Common Stock. In addition, in the first quarter of 2015, the Company allocated $62.6 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 related loss on the debt extinguishment in the first quarter of 2015 was not material. In connection with the Note conversions in the first quarter of 2015, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 146,248 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 $12.3 million, as Treasury Stock during the first quarter 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 may 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 is determined based on the number of warrants with respect to which the warrant holder has closed out its hedge position, provided that the warrant holder does 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 may 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 quarter 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 March 31, 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.

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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 March 31, 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 $164.4 million and $200.5 million for the three months ended March 31, 2016 and 2015, respectively. The Company's effective tax rate was 49.8% and 72.5% for the three months ended March 31, 2016 and 2015, respectively. The Company's effective tax rate for the three months ended March 31, 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, partly offset by the positive impact of the domestic manufacturing deduction and the federal tax credit for increased research activities.

The Company's effective tax rate for the three months ended March 31, 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 Company also recorded an income tax benefit in its Statement of Comprehensive Income of $2.0 million and $2.5 million for the three months ended March 31, 2016 and 2015, respectively, in connection with unrealized gains (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 March 31, 2016 and December 31, 2015 were $44.6 million and $50.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses as of March 31, 2015 and December 31, 2014 were $84.1 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 March 31, 2016, December 31, 2015, and March 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 March 31, 2016, December 31, 2015, and March 31, 2015.

The Company recognized an additional facility lease obligation of $10.8 million during the three months ended March 31, 2015, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased. No such amount was recognized during the three months ended March 31, 2016.

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,

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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 an estimate of 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. The court’s final opinion and judgment are expected to be issued following submission of post-trial briefs, which are expected to be submitted in the second quarter of 2016. The Company and Sanofi plan to appeal any judgment that is adverse to the Company and Sanofi.

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 court deferred a decision on the permanent injunction until after post-trial briefs are submitted.

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

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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 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 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 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 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 November 2, 2015, the court set a tentative trial date beginning on September 27, 2016. At this time, the Company is not able to predict the outcome of, or an estimate of gain or range of possible loss, if any, related to these proceedings.

Proceedings Relating to Shareholder Derivative Claims

On December 30, 2015, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the 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 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 estimate a range of possible loss, if any, relating to these matters.

13. Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-09, Compensation - Stock Compensation. The amendments require 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. The amendments also require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period, and excess tax benefits will be classified as an operating activity in the statement of cash

flows. The tax effects of exercised or vested awards will be treated as discrete items in the reporting period in which they occur. The amendments are effective for annual periods, and interims periods within those annual periods, beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the impact that this guidance will have on the Company's financial statements.

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.

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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. Other than an amendment relating to presenting in comprehensive income the portion of the total change in the fair value of a liability resulting from a change in instrument-specific credit risk (if the entity has elected to measure the liability at fair value), early adoption is not permitted. 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.

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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, 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, dupilumab, 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 income tax obligations, 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 oncology, rheumatoid arthritis (RA), asthma, atopic dermatitis, pain, and infectious diseases.

Our total revenues were $1,200.8 million in the first quarter of 2016, compared to $869.6 million in the first quarter of 2015. Our net income was $165.7 million, or $1.45 per diluted share, in the first quarter of 2016, compared to net income of $76.0 million, or $0.66 per diluted share, in the first quarter 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.

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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. 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 13 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 12 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune® technology.

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Trap-based Clinical Programs

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. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Sarilumab (REGN88)

Antibody to the interleukin-6 receptor

(IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).	
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.
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.

In Phase 2 clinical development for the treatment of wet AMD. Fast Track designation received from the U.S. Food and Drug Administration (FDA) for the treatment of patients with wet AMD.	
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.
Antibody-based Clinical Program in Collaboration with Mitsubishi Tanabe Pharma	
Fasinumab (REGN475)*	Antibody to Nerve Growth Factor (NGF). In Phase 2/3 clinical development (16-week study) for pain due to osteoarthritis and lower back pain. 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/3 study for chronic lower back pain initiated in the first quarter of 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 (antibody to PD-1) in B-cell malignancies.

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* 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

candidate.

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, 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. In the fourth quarter of 2014, Bayer submitted a regulatory application in China for EYLEA for the treatment of wet AMD.

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 $780.9 million in the first quarter of 2016, compared to $541.1 million in the first quarter of 2015. Bayer records revenue from sales of EYLEA outside the United States, which were $418.9 million in the first quarter of 2016, compared to $291.8 million in the first quarter 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 addition, 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. 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 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 were $13.0 million in the first quarter of 2016.

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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 $3.3 million in the first quarter of 2016, compared to $3.5 million in the first quarter of 2015.

Trap-based Clinical Programs

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.

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 was initiated to assess the efficacy and safety of intravitreal aflibercept in patients with moderately severe to severe NPDR without DME.

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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. The most common adverse events (AEs) in the trial 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). Detailed data will be presented at future medical conferences.

In the first quarter of 2016, the 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.

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.

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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.
We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-ONE, SARIL-RA-KAKEHASI (in Japan), and SARIL-RA-HARUKA (long-term safety trial in Japan). In the second quarter of 2015, an open-label, randomized, parallel group, single-dose Phase 1 study to assess the safety of IL-6 receptor blockade with sarilumab or tocilizumab monotherapy in Japanese patients with RA was also initiated. The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe RA who are inadequate responders to either MTX or tumor necrosis factor alpha inhibitor therapy. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, or SARIL-RA-ONE are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.
A BLA for U.S. regulatory approval of sarilumab was accepted for review by the FDA in December 2015. The target date for an FDA decision on the BLA is October 30, 2016.
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. The study is ongoing and will continue through week 52, after which we and Sanofi will determine future development plans.
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 dupilumab 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

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is a serious disease, and preliminary clinical evidence that indicates that the drug may demonstrate substantial improvement over existing therapies.

In 2015, the United Kingdom (UK) Medicines & Healthcare products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) Designation to dupilumab 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 dupilumab 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 dupilumab 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: dupilumab 300 mg subcutaneously once per week, dupilumab 300 mg subcutaneously every two weeks, or placebo for 16 weeks following an initial dupilumab 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 dupilumab 300 mg weekly, and 38% and 36% of patients who received dupilumab 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 dupilumab 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 dupilumab 300 mg weekly, and 51% and 44% of patients who received dupilumab 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% dupilumab and 65%-72% placebo) was comparable between the dupilumab groups and the placebo groups. The proportion of patients who completed the treatment period was 88%-94% for dupilumab and 80.5%-82% for placebo. The rate of serious AEs was 1%-3% for dupilumab and 5%-6% for placebo. Serious and severe infections were also numerically higher in the placebo groups in both studies (0.5%-1% dupilumab and 2%-3% placebo). AEs that were noted to have a higher rate with dupilumab treatment across both studies included injection site reactions (10%-20% dupilumab; 7%-8% placebo) and conjunctivitis (7%-12% dupilumab; 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 will be submitted for presentation at a future medical congress.

In the first quarter of 2015, the Phase 3 LIBERTY AD CAFÉ study of dupilumab in severe atopic dermatitis was initiated. This placebo-controlled study will investigate two dose regimens of dupilumab (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.

Phase 2 Study in Pediatric Patients. In the first quarter of 2015, a Phase 2 pharmacokinetic and safety study in pediatric patients (6-17 years of age) with moderate-to-severe atopic dermatitis was initiated and is fully enrolled.

Asthma

Phase 3 Study. A Phase 3 trial, LIBERTY ASTHMA QUEST, in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015. 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. The global, placebo-controlled Phase 3 study is expected to enroll more than 1,600 patients with uncontrolled persistent asthma and will evaluate two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

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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. 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

Based on clinical results from a Phase 1 study, 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 lower 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.

Clinical Program

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 April 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). The safety analysis includes all results at the time of the primary efficacy analysis; complete data will be reported when all patients complete the full 36 weeks. 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. The Company plans to present detailed results of the study at an upcoming medical congress.

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. A Phase 2b/3 study in chronic lower back pain was also initiated in the first quarter of 2016.

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The fasinumab Phase 3 program is expected to consist of approximately 10,000 patients.

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 dupilumab in the United States. We have not exercised our option to co-promote Praluent 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

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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. 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, Bayer is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. We are eligible to receive a $10.0 million additional development milestone payment from Bayer, although this payment could be reduced by half if Bayer does not opt-in to the collaboration.

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.

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Collaboration with Mitsubishi Tanabe Pharma

Fasinumab Asia. In September 2015, we entered into a collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) providing MTPC with development and commercial rights to fasinumab in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the MTPC Territories). In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment in 2015, and in the first quarter of 2016, MTPC made additional payments of $45.0 million and $15.0 million to us. We are also entitled to receive up to an aggregate of $155.0 million in development milestone and other contingent payments. Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Collaboration with Intellia Therapeutics

In April 2016, we entered into a license and collaboration agreement with Intellia Therapeutics, Inc., a privately held company, 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, and have also agreed to purchase up to $50.0 million of Intellia shares contingent upon Intellia consummating its next equity financing. 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 one-time 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. The terms of the co-development and co-commercialization agreement are expected to be finalized by the end of 2016. Transthyretin amyloidosis (ATTR), the first target selected by us, will be subject to the co-development and co-commercialization arrangement between the parties.

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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 preparation for potential commercialization of our late-stage antibody product candidates, 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	Bayer received regulatory approval for EYLEA for various indications and continued to pursue regulatory applications for marketing approval in additional countries	Bayer to submit for additional regulatory approvals outside the United States for various indications
	Initiated Phase 3 study for the treatment of NPDR in patients without DME	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)	Reported positive results from Phase 3 ODYSSEY ESCAPE trial	Report additional data from Phase 3 ODYSSEY program
	The DMC of the ODYSSEY OUTCOMES study completed the first interim analysis for futility and recommended the study continue with no changes	Submit for additional regulatory approvals outside the United States Regulatory agency and reimbursement authority decisions on applications outside the United States

	Prespecified early-stopping interim analysis by DMC of ODYSSEY OUTCOMES trial
	Filing of supplemental BLA for monthly dosing regimen

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Antibody-based Clinical Programs (continued):

	2016 Events to Date	2016-2017 Plans (next 12 months)
Sarilumab (IL-6R Antibody)	Reported positive top-line results from Phase 3 SARIL-RA-MONARCH trial Regulatory applications submitted in various countries outside the United States	Continue patient enrollment in Phase 3 SARIL-RA program FDA target action date of October 30, 2016 Submit for additional regulatory approvals outside the United States, including the EU and Japan
Dupilumab (IL-4R Antibody)	Reported positive top-line results from Phase 3 LIBERTY AD SOLO 1 and SOLO 2 trials Initiated Phase 3 LIBERTY AD CAFÉ study in atopic dermatitis	Continue patient enrollment in various Phase 2 and Phase 3 studies Complete patient enrollment in Phase 2 EoE and Phase 3 asthma studies Report results from Phase 3 CHRONOS study in atopic dermatitis Complete rolling BLA submission for atopic dermatitis in the United States Initiate Phase 3 study in pediatric patients in atopic dermatitis Initiate Phase 3 study in patients with nasal polyps
REGN2222 (RSV-F Antibody)		Continue patient enrollment in Phase 3 NURSERY Pre-Term study
Fasinumab (NGF Antibody)	Initiated Phase 3 long-term safety and efficacy study in patients with osteoarthritis of knee and hip Initiated Phase 2b/3 study in chronic lower back pain Reported positive top-line results from Phase 2/3 study in patients with osteoarthritis pain	Continue patient enrollment in long-term safety and efficacy study in osteoarthritis and Phase 2b/3 study in chronic lower back pain
Evinacumab (Angptl-3 Antibody)	FDA granted orphan-drug designation for treatment of HoFH Completed Phase 1 study in patients with dyslipidemia	Complete patient enrollment in Phase 2 HoFH study
Rinucumab/aflibercept (PDGFR-beta Antibody co-formulated with aflibercept)		Complete patient enrollment in Phase 2 study Report results from Phase 2 study
Nesvacumab/aflibercept (Ang2 Antibody co-formulated with aflibercept)	Initiated Phase 2 study in wet AMD and DME	Continue patient enrollment in Phase 2 study
Trevogrumab (GDF8 Antibody)		

		Initiate Phase 1 combination therapy studies
REGN2810 (PD-1 Antibody)	Continued patient enrollment in Phase 1 study	Continue patient enrollment in Phase 1 and Phase 2 studies
	Initiated Phase 2 potentially pivotal study for the treatment of advanced cutaneous squamous cell carcinoma	Initiate later-stage pivotal studies
REGN1908-1909 (Feld1 Antibody)	Completed initial proof-of-concept study	Continue early stage development
REGN1979 (CD20 and CD3 Antibody)	Continued patient enrollment in Phase 1 study	Complete patient enrollment in Phase 1 study

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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 March 31, 2016 and 2015

Net Income

Net income for the three months ended March 31, 2016 and 2015 consists of the following:

(In millions)	2016	2015
Revenues	$1,200.8	$869.6
Operating expenses	(871.5)	(586.1)
Other income (expense)	0.8	(7.0)
Income before income taxes	330.1	276.5
Income tax expense	(164.4)	(200.5)
Net income	$165.7	$76.0

Revenues

Revenues for the three months ended March 31, 2016 and 2015 consist of the following:

(In millions)	2016	2015
Net product sales	$784.2	$544.6
Collaboration revenue:		
Sanofi	219.7	173.4
Bayer	179.6	123.8
Total collaboration revenue	399.3	297.2
Other revenue	17.3	27.8
Total revenues	$1,200.8	$869.6

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in 2014, macular edema following BRVO in 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended March 31, 2016, EYLEA net product sales increased to $780.9 million from $541.1 million for the three months ended March 31, 2015 due to higher sales volume. For the three months ended March 31, 2016 and 2015, we also recognized ARCALYST net product sales of $3.3 million and $3.5 million, respectively.

For the three months ended March 31, 2016 and 2015, we recorded 60% and 69%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

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Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, 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	18.9	35.8	2.9	57.6
Credits/payments	(17.5)	(50.4)	(2.5)	(70.4)
Balance as of March 31, 2016	$ 7.8	$ 33.7	$ 0.9	$42.4
Balance as of December 31, 2014	$ 3.1	$ 21.2	$ 0.5	$24.8
Provision related to current period sales	11.4	24.7	1.4	37.5
Credits/payments	(9.8)	(13.0)	(1.4)	(24.2)
Balance as of March 31, 2015	$ 4.7	$ 32.9	$ 0.5	$38.1

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 March 31,	
(In millions)	2016	2015
Antibody:		
Reimbursement of Regeneron research and development expenses	$193.6	$168.8
Reimbursement of Regeneron commercialization-related expenses	73.3	8.5
Regeneron's share of losses in connection with commercialization of antibodies	(99.4)	(22.4)
Other	2.9	2.6
Total Antibody	170.4	157.5
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	29.3	—
Other	20.0	—
Total Immuno-oncology	49.3	—
ZALTRAP:		
Reimbursement of Regeneron research and development expenses	—	0.7
Other	—	15.2
Total ZALTRAP	—	15.9
Total Sanofi collaboration revenue	$219.7	$173.4

In the first quarter of 2016, Sanofi's reimbursement of our antibody research and development expenses consisted of $57.4 million under our Antibody Discovery Agreement and $136.2 million under our License and Collaboration Agreement, compared to $46.0 million and $122.8 million, respectively, in the first quarter of 2015. The higher reimbursement of research and development costs in the first quarter of 2016, compared to the same period in 2015, was primarily due to increased development activities for

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dupilumab, partly offset by (i) decreased development activities for Praluent, and (ii) the fact that in 2016, Sanofi no longer co-develops and reimburses us for development activities for REGN1033 and 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, dupilumab.

During the three months ended March 31, 2015, we and Sanofi shared pre-launch commercial expenses, including those incurred by Sanofi, related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In addition, effective in the first quarter of 2016, we and Sanofi also began sharing pre-launch commercialization expenses related to dupilumab. As such, we recorded our share of losses in connection with preparing to commercialize Praluent, sarilumab, and dupilumab within Sanofi collaboration revenue. 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. 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. We and Sanofi incurred higher commercialization expenses for Praluent in the first quarter of 2016, compared to the same period in 2015, primarily in connection with launching the product in the United States and certain European countries. Praluent net product sales, which are recorded by Sanofi, were $13.0 million in the first quarter of 2016.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of March 31, 2016, $64.0 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

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 quarter of 2016, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $20.1 million under our IO Discovery Agreement, and $9.2 million under our IO License and Collaboration Agreement related to REGN2810.

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 March 31, 2016, $580.0 million of the up-front payments was deferred and will be recognized ratably as revenue in future periods.

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 pays us 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, 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.

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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.