REGENERON PHARMACEUTICALS INC
Form 10-Q
May 07, 2015
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, 2015

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 16, 2015:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,971,868
Common Stock, $.001 par value	101,305,623

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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, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$507,907	$648,719
Marketable securities	234,257	251,761
Accounts receivable - trade, net	1,015,962	739,379
Accounts receivable from Sanofi	159,444	121,058
Accounts receivable from Bayer HealthCare	163,056	156,962
Inventories	133,863	128,861
Deferred tax assets	62,126	49,235
Prepaid expenses and other current assets	34,099	71,486
Total current assets	2,310,714	2,167,461
Marketable securities	483,305	460,154
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	1,110,597	974,309
Deferred tax assets	289,484	289,021
Other assets	4,473	3,034
Total assets	$4,198,573	$3,893,979
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$462,762	$483,489
Deferred revenue from Sanofi, current portion	19,342	15,927
Deferred revenue - other, current portion	51,845	58,098
Other current liabilities	2,185	97,146
Total current liabilities	536,134	654,660
Deferred revenue from Sanofi	48,656	72,367
Deferred revenue - other	114,318	103,909
Facility lease obligations	328,394	310,938
Convertible senior notes	144,082	146,773
Other long-term liabilities	55,559	40,855
Total liabilities	1,227,143	1,329,502
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 - 1,971,868 in 2015 and 1,973,368 in 2014	2	2
Common Stock, $.001 par value; 160,000,000 shares authorized; shares issued - 103,418,736 in 2015 and 102,475,154 in 2014	103	102

Additional paid-in capital	2,812,573	2,465,008
Retained earnings	292,665	216,644
Accumulated other comprehensive income	47,904	52,251
Treasury stock, at cost; 2,163,980 shares in 2015 and 2,017,732 in 2014	(181,817)	(169,530)
Total stockholders' equity	2,971,430	2,564,477
Total liabilities and stockholders' equity	$4,198,573	$3,893,979

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,	
	2015	2014
Statements of Operations		
Revenues:		
Net product sales	$544,573	$362,378
Sanofi collaboration revenue	173,356	130,508
Bayer HealthCare collaboration revenue	123,846	125,312
Technology licensing and other revenue	27,837	7,542
	869,612	625,740
Expenses:		
Research and development	343,113	287,379
Selling, general, and administrative	158,991	103,227
Cost of goods sold	42,570	27,473
Cost of collaboration and contract manufacturing	41,385	16,099
	586,059	434,178
Income from operations	283,553	191,562
Other income (expense):		
Investment and other income	81	937
Interest expense	(6,169)	(11,613)
Loss on extinguishment of debt	(942)	—
	(7,030)	(10,676)
Income before income taxes	276,523	180,886
Income tax expense	(200,502)	(112,581)
Net income	$76,021	$68,305
Net income per share - basic	$0.74	$0.69
Net income per share - diluted	$0.66	$0.61
Weighted average shares outstanding - basic	102,227	98,709
Weighted average shares outstanding - diluted	114,519	112,151
Statements of Comprehensive Income		
Net income	$76,021	$68,305
Other comprehensive (loss) income:		
Unrealized (loss) gain on marketable securities, net of tax	(4,347)	2,653
Comprehensive income	$71,674	$70,958

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,	
	2015	2014
Cash flows from operating activities:		
Net income	$76,021	$68,305
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	16,027	11,530
Non-cash compensation expense	103,759	75,785
Non-cash interest expense	2,358	5,916
Loss on extinguishment of debt	942	—
Other non-cash charges and expenses, net	6,006	3,761
Deferred taxes	(10,888)	(5,761)
Changes in assets and liabilities:		
Increase in Sanofi, Bayer HealthCare, and trade accounts receivable	(321,063)	(92,529)
Increase in inventories	(5,932)	(15,550)
Decrease (increase) in prepaid expenses and other assets	35,874	(20,898)
(Decrease) increase in deferred revenue	(16,140)	37,107
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	25,534	(14,139)
Total adjustments	(163,523)	(14,778)
Net cash (used in) provided by operating activities	(87,502)	53,527
Cash flows from investing activities:		
Purchases of marketable securities	(95,775)	(253,878)
Sales or maturities of marketable securities	80,456	82,469
Capital expenditures	(114,162)	(64,822)
Net cash used in investing activities	(129,481)	(236,231)
Cash flows from financing activities:		
Proceeds (payments) in connection with facility and capital lease obligations	6,738	(262)
Repayments of convertible senior notes	(16,686)	—
Payments in connection with reduction of outstanding warrants	(124,531)	—
Proceeds from issuance of Common Stock	76,273	55,042
Payments in connection with Common Stock tendered for employee tax obligations	(21,192)	(63,086)
Excess tax benefit from stock-based compensation	155,569	117,260
Net cash provided by financing activities	76,171	108,954
Net decrease in cash and cash equivalents	(140,812)	(73,750)
Cash and cash equivalents at beginning of period	648,719	535,608
Cash and cash equivalents at end of period	$507,907	$461,858

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. ("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, 2014 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, 2014.
Certain reclassifications have been made to prior period amounts to conform with the current period’s presentation.
In addition, the previously issued (i) Consolidated Balance Sheet as of December 31, 2014 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and (ii) Condensed Consolidated Statement of Operations and Comprehensive Income for the three months ended March 31, 2014 and Condensed Consolidated Statement of Cash Flows for the three months ended March 31, 2014 contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, have each been revised in this Quarterly Report on Form 10-Q to reflect a correction in the Company's accounting for certain stock option awards. See Note 4.

2. Product Sales

EYLEA® net product sales in the United States totaled $541.1 million and $359.0 million for the three months ended March 31, 2015 and 2014, respectively. In addition, ARCALYST® net product sales totaled $3.5 million and $3.4 million for the three months ended March 31, 2015 and 2014, respectively.
For the three months ended March 31, 2015 and 2014, the Company recorded 69% and 79%, 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, 2015 and 2014.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
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
Balance as of December 31, 2013	$4,400	$19,663	$538	$24,601
Provision related to current period sales	6,886	16,858	448	24,192
Credits/payments	(6,664)	(16,310)	(454)	(23,428)
Balance as of March 31, 2014	$4,622	$20,211	$532	$25,365

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

3. Collaboration Agreements

a. Sanofi

Sanofi collaboration revenue, as detailed below, consisted primarily of (i) recognition of previously deferred revenue related to the companies' ZALTRAP® collaboration agreement, and (ii) reimbursement for research and development expenses that the Company incurred, partly offset by sharing of pre-launch commercialization expenses, in connection with the companies' antibody collaboration.

	Three Months Ended March 31,	
Sanofi Collaboration Revenue	2015	2014
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	$(3,212)
Reimbursement of Regeneron research and development expenses	$686	1,092
Other	15,236	2,177
Total ZALTRAP	15,922	57
Antibody:		
Reimbursement of Regeneron research and development expenses	168,820	126,822
Reimbursement of Regeneron commercialization-related expenses	8,458	—
Regeneron's share of losses in connection with commercialization of antibodies	(22,405)	—
Other	2,561	3,629
Total Antibody	157,434	130,451
	$173,356	$130,508

ZALTRAP

In September 2003, the Company entered into a collaboration agreement ("ZALTRAP Collaboration Agreement") with Aventis Pharmaceuticals Inc. (predecessor to Sanofi U.S.) to jointly develop and commercialize ZALTRAP. Under the terms of the ZALTRAP Collaboration Agreement, as amended, Regeneron and Sanofi shared co-promotion rights and profits and losses on sales of ZALTRAP outside of Japan, and the Company was entitled to receive a percentage of sales of ZALTRAP in Japan. Sanofi commenced sales of ZALTRAP (ziv-aflibercept) Injection for Intravenous Infusion, in combination with 5-fluorouracil, leucovorin, irinotecan ("FOLFIRI"), for patients with metastatic colorectal cancer ("mCRC") that is resistant to or has progressed following an oxaliplatin-containing regimen, in the United States in the third quarter of 2012 and in certain European and other countries in the first quarter of 2013.

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"), with an effective date of July 1, 2014. Under the terms of the Amended ZALTRAP Agreement, Sanofi will be solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay the Company a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. The Company will also be paid for all quantities of

ZALTRAP manufactured by it, pursuant to a supply agreement, through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities, or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement. Unless terminated earlier in accordance with

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REGENERON PHARMACEUTICALS, INC.
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its provisions, the Amended ZALTRAP Agreement will continue to be in effect until such time as neither Sanofi nor its affiliates or sublicensees is developing or commercializing ZALTRAP.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015 the Company recognized $14.9 million of previously 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 exists, and (ii) the unamortized portion of up-front payments from Sanofi as the Company has no further performance obligations. In addition, in the first quarter of 2015, the Company recorded $19.8 million in technology licensing and other revenue, primarily related to (i) revenues earned from Sanofi based on a percentage of net sales of ZALTRAP and (ii) revenues earned from Sanofi for manufacturing ZALTRAP commercial supplies.

Antibodies

Under the Company's antibody collaboration agreement with Sanofi, agreed upon worldwide research and development expenses incurred by both companies during the term of the agreement 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, 2015 and 2014, the Company recognized as additional research and development expense $25.0 million and $23.8 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent® and sarilumab.

Effective in the second and fourth quarters of 2014, the Company and Sanofi began sharing pre-launch commercialization expenses related to Praluent and sarilumab, respectively, in accordance with the companies' antibody collaboration agreement.

In May 2013, the Company acquired from Sanofi full exclusive rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors and ligands in opthalmology. With respect to PDGF antibodies, the Company made two $5.0 million development milestone payments to Sanofi in the first quarter of 2014, which were recorded as research and development expense. The Company is also obligated to pay up to $30.0 million in additional potential development milestones as well as royalties on any future sales of PDGF antibodies.

b. Bayer HealthCare LLC

The Company and Bayer HealthCare globally collaborate on the development and commercialization of EYLEA outside of the United States. In addition, in January 2014, the Company entered into a license and collaboration agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta).

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

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

	Three Months Ended March 31,	
Bayer HealthCare Collaboration Revenue	2015	2014
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$89,426	$61,159
Sales milestones	15,000	30,000
Cost-sharing of Regeneron EYLEA development expenses	2,657	20,347
Other	12,912	10,932
Total EYLEA	119,995	122,438
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	1,254	513
Other	2,597	2,361
Total PDGFR-beta	3,851	2,874
Total Bayer HealthCare collaboration revenue	$123,846	$125,312

EYLEA outside the United States

In the first quarter of 2015, the Company earned a $15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. In the first quarter of 2014, the Company earned two $15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million and $600 million, respectively, over a twelve-month period.

In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following branch retinal vein occlusion ("BRVO"). In connection with this decision, Bayer HealthCare reimbursed Regeneron $15.7 million for a defined share of the EYLEA global development costs that the Company had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014 and is included with "Cost-sharing of Regeneron EYLEA development expenses" in the table above. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). The Company is entitled to receive a tiered percentage of EYLEA net sales in Japan.

PDGFR-beta antibody outside the United States

In January 2014, the Company entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to the Company in January 2014, and 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. The $25.5 million upfront payment was initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. Bayer HealthCare is also obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to the Company in the first quarter of 2014 (both of which, for the purpose of revenue recognition, were not considered substantive).

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

4. Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's 2014 Long-Term Incentive Plan based on the grant-date fair value of those awards. The Company recognized stock-based compensation expense of $103.8 million and $75.8 million in the first quarter of 2015 and 2014, respectively.

Revisions of Previously-Issued Financial Statements

During the first quarter of 2015, the Company determined that for certain stock option awards granted to an employee in prior periods, the incorrect requisite service period was utilized in determining the period over which the related compensation expense should have been recorded. Such awards were made as part of the Company's annual employee option grants in December of each applicable year. As a result, compensation expense for the three months and years ended December 31, 2014 and 2013 was understated, and compensation expense for the three months ended March 31, 2014 and 2013, June 30, 2014 and 2013, and September 30, 2014 and 2013 was overstated. These revisions consisted entirely of non-cash adjustments, and therefore had no impact on the Company's previously reported total cash flows from operating activities and total cash flows in its Statements of Cash Flows. The Company evaluated the impact of these items on prior periods, assessing materiality quantitatively and qualitatively, and concluded that the errors were not considered to be material to any previously-issued quarterly or annual financial statements. However, the Company concluded that it would revise the applicable prior period amounts in this filing to reflect the impact of these corrections because the cumulative amount of such corrections is expected to be material to the year ending December 31, 2015. The Company's prior-period financial statements will reflect these revisions for the applicable periods presented in future filings.

The table below presents the impact of these revisions, including the related tax effect, on the Company's previously-filed 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)

	December 31, 2014		
	As Previously Reported	Adjustments	As Revised
Balance Sheet Data:			
Deferred tax assets (noncurrent)	$266,869	$22,152	$289,021
Total assets	3,871,827	22,152	3,893,979
Additional paid-in capital	2,404,118	60,890	2,465,008
Retained earnings	255,382	(38,738)	216,644
Total stockholders' equity	2,542,325	22,152	2,564,477
Total liabilities and stockholders' equity	3,871,827	22,152	3,893,979

	Three Months Ended March 31, 2014		
	As Previously Reported	Adjustments	As Revised
Consolidated Statement of Operations Data:			
Selling, general, and administrative	$108,850	$(5,623)	$103,227
Total operating expenses	439,801	(5,623)	434,178
Income from operations	185,939	5,623	191,562
Income before income taxes	175,263	5,623	180,886
Income tax expense	109,820	2,761	112,581
Net income	65,443	2,862	68,305
Net income per share - basic	$0.66	$0.03	$0.69
Net income per share - diluted	$0.58	$0.03	$0.61
Consolidated Statement of Cash Flows Data:			
Cash flows from operating activities			
Net income	$65,443	$2,862	$68,305
Non-cash compensation expense	81,408	(5,623)	75,785
Deferred taxes	(8,522)	2,761	(5,761)

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

The tables below present the impact of these revisions, including the related tax effects, on additional previously-filed interim and year-end Consolidated Statements of Operations (i) for the three and six months ended June 30, 2014, (ii) for the three and nine months ended September 30, 2014, and (iii) for the three months and year ended December 31, 2014.

	Three Months Ended June 30, 2014			Six Months Ended June 30, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Selling, general, and administrative	$102,414	$(5,684)	$96,730	$211,264	$(11,307)	$199,957
Total operating expenses	443,294	(5,684)	437,610	883,095	(11,307)	871,788
Income from operations	222,406	5,684	228,090	408,345	11,307	419,652
Income before income taxes	203,119	5,684	208,803	378,382	11,307	389,689
Income tax expense	110,384	2,068	112,452	220,204	4,829	225,033
Net income	92,735	3,616	96,351	158,178	6,478	164,656
Net income per share - basic	$0.92	$0.04	$0.96	$1.58	$0.07	$1.65
Net income per share - diluted	$0.82	$0.03	$0.85	$1.40	$0.06	$1.46

	Three Months Ended September 30, 2014			Nine Months Ended September 30, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Selling, general, and administrative	$149,748	$(5,745)	$144,003	$361,012	$(17,052)	$343,960
Total operating expenses	543,069	(5,745)	537,324	1,426,164	(17,052)	1,409,112
Income from operations	182,719	5,745	188,464	591,064	17,052	608,116
Income before income taxes	176,078	5,745	181,823	554,460	17,052	571,512
Income tax expense	96,358	2,090	98,448	316,562	6,919	323,481
Net income	79,720	3,655	83,375	237,898	10,133	248,031
Net income per share - basic	$0.79	$0.04	$0.83	$2.37	$0.10	$2.47
Net income per share - diluted	$0.70	$0.03	$0.73	$2.10	$0.09	$2.19

	Three Months Ended December 31, 2014			Year Ended December 31, 2014		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Selling, general, and administrative	$143,743	$31,564	$175,307	$504,755	$14,512	$519,267
Total operating expenses	554,962	31,564	586,526	1,981,126	14,512	1,995,638
Income from operations	247,367	(31,564)	215,803	838,431	(14,512)	823,919
Income before income taxes	221,287	(31,564)	189,723	775,747	(14,512)	761,235

Income tax expense	111,111	(11,483	) 99,628	427,673	(4,564	) 423,109
Net income	110,176	(20,081	) 90,095	348,074	(9,948	) 338,126
Net income per share - basic	$1.09	$(0.20	) $0.89	$3.46	$(0.10	) $3.36
Net income per share - diluted	$0.96	$(0.18	) $0.78	$3.07	$(0.09	) $2.98

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5. 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,	
	2015	2014
Net income - basic and diluted	$76,021	$68,305
(Shares in thousands)		
Weighted average shares - basic	102,227	98,709
Effect of dilutive securities:		
Stock options	9,313	9,879
Restricted stock	467	401
Warrants	2,512	3,162
Dilutive potential shares	12,292	13,442
Weighted average shares - diluted	114,519	112,151
Net income per share - basic	$0.74	$0.69
Net income per share - diluted	$0.66	$0.61

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)	2015	2014
Stock options	3,673	3,646
Convertible senior notes	1,929	4,761

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6. Marketable Securities

Marketable securities as of March 31, 2015 and December 31, 2014 consist of both debt securities issued by investment grade institutions as well as equity securities. The Company also held restricted marketable securities as of December 31, 2014, consisting of the Company's investment in Avalanche Biotechnologies, Inc. common shares, which were subject to customary transfer restrictions until January 2015 under a lock-up agreement with the underwriters of Avalanche's initial public offering.

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

As of March 31, 2015	Amortized Cost Basis	Unrealized Gains	Losses	Fair Value
Unrestricted				
Corporate bonds	$530,693	$898	$(99)	$531,492
U.S. government and government agency obligations	56,433	201	—	56,634
Municipal bonds	39,807	52	(3)	39,856
Equity securities	17,005	72,575	—	89,580
	$643,938	$73,726	$(102)	$717,562
As of December 31, 2014				
Unrestricted				
Corporate bonds	$548,832	$136	$(1,462)	$547,506
U.S. government and government agency obligations	28,596	3	(46)	28,553
Municipal bonds	37,044	37	(43)	37,038
Equity securities	2,005	5,374	—	7,379
	616,477	5,550	(1,551)	620,476
Restricted				
Equity securities	15,000	76,439	—	91,439
	$631,477	$81,989	$(1,551)	$711,915

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of March 31, 2015 mature at various dates through August 2024. The fair values of debt security investments by contractual maturity consist of the following:

	March 31, 2015	December 31, 2014
Maturities within one year	$234,257	$251,761
Maturities after one year through five years	392,624	360,208
Maturities after five years through ten years	1,101	1,128
	$627,982	$613,097

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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, 2015	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$136,720	$(85)	$4,139	$(14)	$140,859	$(99)
Municipal bonds	3,938	(3)	—	—	3,938	(3)
	$140,658	$(88)	$4,139	$(14)	$144,797	$(102)
As of December 31, 2014						
Corporate bonds	$390,613	$(1,462)	—	—	$390,613	$(1,462)
U.S. government and government agency obligations	25,549	(46)	—	—	25,549	(46)
Municipal bonds	10,779	(43)	—	—	10,779	(43)
	$426,941	$(1,551)	—	—	$426,941	$(1,551)

For the three months ended March 31, 2015 and 2014, total realized gains and losses on sales of marketable securities were not material.

Changes in the Company's accumulated other comprehensive income (loss) for the three months ended March 31, 2015 and 2014 related to unrealized gains and losses on available-for-sale marketable securities. For the three months ended March 31, 2015 and 2014, 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.

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7. 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, 2015	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:			
Unrestricted			
Corporate bonds	$531,492	—	$531,492
U.S. government and government agency obligations	56,634	—	56,634
Municipal bonds	39,856	—	39,856
Equity securities	89,580	$89,580	—
	$717,562	$89,580	$627,982
As of December 31, 2014			
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$547,506	—	$547,506
U.S. government and government agency obligations	28,553	—	28,553
Municipal bonds	37,038	—	37,038
Equity securities	7,379	$7,379	—
	620,476	7,379	613,097
Restricted			
Equity securities	91,439	—	91,439
	$711,915	$7,379	$704,536

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, 2015 and 2014.

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, 2015 and 2014.

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 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, 2015, and there were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2014.

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As of March 31, 2015 and December 31, 2014, the Company had $162.7 million and $169.4 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") that will mature on October 1, 2016 unless earlier converted or repurchased. As described in Note 10, a portion of the Notes was surrendered for conversion during the first quarter of 2015. The fair value of the outstanding Notes was estimated to be $876.0 million and $819.8 million as of March 31, 2015 and December 31, 2014, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

Additionally, as described in Note 10, pursuant to a November 2014 amendment agreement with a warrant holder, a portion of the Company's warrants were classified as a liability and measured at fair value as of December 31, 2014. The fair value of this liability was estimated to be $87.5 million as of December 31, 2014, and was determined based on Level 2 inputs, such as market and observable sources. During the first quarter of 2015, upon expiration of the November 2014 amendment agreement, the remaining warrants were re-measured at fair value and reclassified back to additional paid-in capital.

8. Inventories

Inventories consist of the following:

	March 31, 2015	December 31, 2014
Raw materials	$9,644	$10,923
Work-in-process	83,990	73,519
Finished goods	11,398	10,768
Deferred costs	28,831	33,651
	$133,863	$128,861

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

9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2015	December 31, 2014
Accounts payable	$90,601	$99,508
Accrued payroll and related costs	64,112	92,778
Accrued clinical trial expense	44,659	41,555
Accrued sales-related charges, deductions, and royalties	165,511	133,085
Other accrued expenses and liabilities	97,879	116,563
	$462,762	$483,489

10. Debt

a. Convertible Debt

In the first quarter of 2015, the Company settled conversion obligations for $16.7 million principal amount of the Company's original $400.0 million aggregate principal amount of Notes that was previously surrendered for conversion. In accordance with the terms of the Notes, the Company elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of the Company's Common Stock in respect of any amounts due in excess thereof. Consequently, in the first quarter of 2015, the Company (i) paid $16.7 million in cash, (ii) issued 146,253 shares

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of Common Stock, and (iii) 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. In addition, the Company recognized a $0.9 million loss on the debt extinguishment in connection with the Notes that were surrendered for conversion during the first quarter of 2015.

In connection with the initial offering of the Notes in October 2011, the Company entered into convertible note hedge and warrant transactions with multiple counterparties, which were recorded to additional paid-in capital. As a result of the Note conversions described above, 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.

In addition to the Note conversions described above, the Company received notification in April 2015 that an additional $127.3 million principal amount of the Notes were surrendered for conversion, and settlement is anticipated during the second quarter of 2015. The Company has elected to settle the related conversion obligations through a combination of cash and shares (total payment will be based on 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 equivalent to the number of shares the Company will be required to issue to settle the non-cash portion of the related Note conversions.

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 by up to a maximum of 493,229. 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 493,229 warrants 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. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2014, the Company recorded a $59.8 million accrued liability as of December 31, 2014 in connection with the warrant holder reducing the number of warrants it held. During the first quarter of 2015, the warrant holder closed out additional portions of its hedge position, and, as a result, 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, 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.

Additionally, in February 2015, the Company entered into another amendment agreement with the same warrant holder whereby the parties agreed to further reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 76,749, for an aggregate amount payable by the Company not to exceed $24.0 million. The reduction in the number of warrants will be 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 $408.00 per share, during the period starting on March 2, 2015 and ending no later than May 7, 2015. The Company may settle, at its option, any payments due under the amendment agreement in cash or by

delivering shares of Common Stock within three days following the warrant holder closing out its hedge position. Therefore, any payments made under the amendment agreement will be recorded to additional paid-in capital, consistent with the original accounting for the warrants under the 2011 issuance. During the first quarter of 2015, the reduction in the number of warrants in accordance with the February 2015 amended agreement was not material.

b. Credit Facility

In March 2015, the Company entered into an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes an option for the Company to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for the

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Company to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty.

Any loans under the Credit Facility have a variable interest rate based on either the London Interbank Offered Rate ("LIBOR") or an alternate base rate, plus an applicable margin that varies with the Company's debt rating and total leverage ratio. The Company had no borrowings outstanding under the Credit Facility as of March 31, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. The Company was in compliance with all covenants of the Credit Facility as of March 31, 2015.

11. 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 $200.5 million and $112.6 million for the three months ended March 31, 2015 and 2014, respectively. The Company's effective tax rate was 72.5% and 62.2% for the three months ended March 31, 2015 and 2014, respectively. The Company's effective tax rate for the three months ended March 31, 2015 was negatively impacted by (i) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, (ii) the non-deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities.

The Company's effective tax rate for the three months ended March 31, 2014 was negatively impacted by (i) expiration at the end of 2013 of the federal tax credit for increased research activities, (ii) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, and (iii) New York state tax legislation enacted in the first quarter of 2014. This tax legislation reduced the New York state income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the Company reducing its related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in the Company's effective tax rate by 10.4% for the first quarter of 2014.

The Company also recorded an income tax benefit in its Statement of Comprehensive Income of $2.5 million for the three months ended March 31, 2015, in connection with unrealized gains (losses) on available-for-sale marketable securities. For the three months ended March 31, 2014, no such income tax provision or benefit was required.

12. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

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 March 31, 2014 and December 31, 2013 were $17.6 million and $16.1 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 convertible senior notes. No such amounts were payable as of March 31, 2014 and December 31, 2013, and the amount of such conversion settlement obligation was not material as of 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. See Note 10. There were no such liabilities recorded in connection with warrants as of March 31, 2015, March 31, 2014, and December 31, 2013.

The Company recognized a facility lease obligation of $10.8 million and $19.4 million during the three months ended March 31, 2015 and 2014, respectively, in connection with capitalizing, on the Company's books, the landlord's costs

of constructing new facilities that the Company has leased.

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Subsequent event

In April 2015, the Company acquired an approximate 100-acre parcel of undeveloped land adjacent to its current Tarrytown, New York location for an aggregate purchase price of $73.0 million. The Company intends to develop this property to accommodate and support its growth, primarily in connection with expanding its existing research and development and office space.

13. 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 and '018 Patent

The Company is a party to patent infringement litigation involving its European Patent No. 1,360,287 (the "'287 Patent") and its U.S. Patent No. 8,502,018 (the "'018 Patent"), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings (the "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), the Company claims infringement of several claims of the '287 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 and the '018 Patent (as applicable). At this time the Company is not able to predict the outcome of, or an estimate of gain, if any, related to, these proceedings.

Proceedings Relating to PCSK9 Antibody (Praluent)

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, the antibody to PCSK9 for LDL cholesterol reduction 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, and 8,859,741 in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 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. This matter has not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to estimate a range of possible loss, if any.

14. Recently Issued Accounting Standards

In May 2014, the FASB issued a new standard related to revenue recognition, 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. The new standard will be effective for annual and interim reporting periods beginning after December 15, 2016, and early adoption is not permitted. 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 Regeneron's human genetics initiative; 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 Praluent® (alirocumab), sarilumab, and dupilumab; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA®), 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, 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 and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis (RA), asthma, and atopic dermatitis.

Our total revenues were $869.6 million in the first quarter of 2015, compared to $625.7 million in the first quarter 2014. Our net income was $76.0 million, or $0.66 per diluted share, in the first quarter of 2015, compared to net income of $68.3 million, or $0.61 per diluted share, in the first quarter of 2014. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have two marketed products:

- EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD), macular edema following central retinal vein occlusion (CRVO), and diabetic macular edema (DME). In addition, (i) in October 2014 and February 2015, the U.S. Food and Drug Administration (FDA) and European Commission, respectively, approved EYLEA for the treatment of macular edema following retinal vein occlusion (RVO), which includes macular edema following branch retinal vein

occlusion (BRVO), (ii) in September 2014, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved EYLEA for myopic choroidal neovascularization (mCNV), and (iii) in March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO and BRVO, DME, and mCNV pending in other countries. We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States.

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- 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.

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 will be solely responsible for the development and commercialization of ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. Refer to "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP" below for further details of the Amended ZALTRAP Agreement. ZALTRAP is currently available in the United States, EU, and certain other countries for treatment, in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

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

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Trap-based Clinical Programs

EYLEA

In Phase 3 clinical development for the treatment of wet AMD (Asia) and DME (Asia) in collaboration with Bayer HealthCare. As described below, EYLEA is also being studied in combination with (i) an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) an antibody to angiopoietin-2 (Ang2).

Antibody-based Clinical Programs in Collaboration with Sanofi

Praluent (alirocumab)

Antibody to PCSK9. In Phase 3 clinical development for low-density lipoprotein (LDL) cholesterol reduction and for the prevention of cardiovascular events.

Sarilumab (REGN88)

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

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 children (Phase 2), asthma (Phase 3), nasal polyps in patients who also have chronic sinusitis (NPwCS) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).

REGN1033

Antibody to myostatin (GDF8). In Phase 2 clinical development in skeletal muscle disorders.

REGN2222

Antibody against respiratory syncytial virus (RSV). In Phase 1 clinical development. In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015, and will be entitled to receive royalties on any future sales of the product candidate.

Antibody-based Clinical Programs in Collaboration with Bayer HealthCare

REGN2176-3

Combination product comprised of an antibody to PDGFR-beta co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. Phase 2 clinical study for the treatment of wet AMD initiated in the second quarter of 2015.

Antibody-based Clinical Programs Developing Independently

REGN1908-1909*

Antibody combination in Phase 1/Phase 2 clinical development against allergic disease.

REGN1500*

Antibody to Angptl-3. Phase 2 clinical study for the treatment of dyslipidemia in homozygous familial hypercholesterolemia initiated in the first quarter of 2015. Studies are ongoing under a partial clinical hold by the FDA that excludes women of childbearing potential.

REGN1400

Antibody to ErbB3. In Phase 1 clinical development in oncology.

REGN1154*

Antibody against an undisclosed target. Phase 1 clinical study in Australia completed.

REGN1193*

Antibody in Phase 1 clinical development against an undisclosed target.

REGN1979

Bispecific antibody against CD20 and CD3. In Phase 1 clinical development in oncology.

REGN910-3**

Combination product comprised of an antibody to Ang2 co-formulated with EYLEA for use in ophthalmology, via intravitreal administration. In Phase 1 clinical development for the treatment of wet AMD and DME.

REGN2810*

Antibody to PD-1. Phase 1 clinical study in oncology initiated in the first quarter of 2015.

Fasinumab (REGN475)*

Antibody to Nerve Growth Factor (NGF). In development for the treatment of pain; currently on partial clinical hold by the FDA limiting duration of trials in osteoarthritis to 16 weeks.

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* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate and we have sole global rights. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on any future sales of the product candidate.

** We acquired from Sanofi full exclusive rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, which were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive a potential development milestone 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.

In 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC (RGC). RGC performs sequencing and genotyping to generate de-identified genomic data. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC is undertaking both large population-based efforts as well as family- and founder-based approaches. RGC leverages laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 70,000 unique samples per year.

Marketed Products

EYLEA (aflibercept) Injection

We commenced sales of EYLEA in the United States for the treatment of wet AMD in November 2011, macular edema following CRVO in September 2012, DME in July 2014, and macular edema following RVO in October 2014. In addition, in March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME. Outside the United States, Bayer HealthCare commenced sales of EYLEA for the treatment of wet AMD in the fourth quarter of 2012, macular edema secondary to CRVO in the fourth quarter of 2013, visual impairment due to DME in the third quarter of 2014, and mCNV in Japan in the fourth quarter of 2014. In February 2015, the European Commission approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. In the fourth quarter of 2014, Bayer HealthCare submitted a regulatory application in China for EYLEA for the treatment of wet AMD. In addition, Bayer HealthCare has submitted an application to the MHLW seeking marketing authorization in Japan for EYLEA for the treatment of macular edema following BRVO. Bayer HealthCare has additional regulatory applications for EYLEA for the treatment of wet AMD, macular edema secondary to CRVO and BRVO, DME, and mCNV pending in other countries.

We are collaborating with Bayer HealthCare on the global development and commercialization of EYLEA outside the United States. Bayer HealthCare 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 $541.1 million in the first quarter of 2015, compared to $359.0 million in the first quarter of 2014. Bayer HealthCare records revenue from sales of EYLEA outside the United States,

which were $291.8 million in the first quarter of 2015, compared to $218.1 million in the first quarter of 2014.

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 $3.5 million in the first quarter of 2015, compared to $3.4 million in the first quarter of 2014.

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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.

DME

Phase 3 VISTA-DME and VIVID-DME Trials. We conducted the VISTA-DME study in the United States, and Bayer HealthCare is conducting the VIVID-DME study in Europe, Japan, and Australia. Patients in both trials were randomized to receive either EYLEA 2 mg monthly, EYLEA 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation. The VIVID-DME trial will continue as planned up to 148 weeks.

In March 2015, the FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME.

Phase 3 VIVID EAST-DME Study. In February 2013, we and Bayer HealthCare initiated a Phase 3 study to evaluate the efficacy and safety of EYLEA in DME in Russia, China, and other Asian countries (VIVID EAST-DME). This trial is fully enrolled.

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, that is intended to lower LDL cholesterol.

Clinical Programs

Phase 3 ODYSSEY Program. We and Sanofi initiated the global Phase 3 ODYSSEY program for Praluent in the second quarter of 2012. The ODYSSEY program consists of more than 23,500 patients, and includes clinical trials evaluating the effect of Praluent, dosed every two weeks, on lowering LDL cholesterol. In addition, the potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial. LDL cholesterol reduction is the primary efficacy endpoint for initial regulatory

filings. Additionally, the ODYSSEY program 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 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. The ODYSSEY studies are being

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conducted in clinical centers around the world including North America, Western and Eastern Europe, South America, Australia, and Asia.

In 2013, we and Sanofi reported data from the ODYSSEY MONO trial, which evaluated the efficacy and safety of Praluent monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. In 2014, we and Sanofi reported detailed positive results from nine additional Phase 3 ODYSSEY studies. All ten studies (ODYSSEY MONO, LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II, and ALTERNATIVE) met their primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at 24 weeks compared to placebo or active comparator. Based on the positive results of these studies, a Biologics License Application (BLA) for U.S. regulatory approval of Praluent was submitted, and accepted by the FDA in January 2015. An FDA rare pediatric disease priority review voucher was utilized in connection with this BLA submission, as a result of which the submission was accepted by the FDA for priority review; the target date for an FDA decision on the BLA is July 24, 2015. The FDA's Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) is scheduled to meet on June 9, 2015 to discuss the BLA for Praluent. In addition, the European Medicines Agency (EMA) has accepted for review the Marketing Authorization Application (MAA) for Praluent.

All patients in the ten trials received Praluent in addition to standard-of care lipid-lowering therapy, with the exception of patients in ODYSSEY MONO. The ODYSSEY ALTERNATIVE trial specifically focused on patients with a history of documented statin intolerance but allowed patients who were taking certain non-statin lipid-lowering therapies to participate in the trial. The trials included patients with LDL-C not at goal with or without a documented history of cardiovascular disease, including hypercholesterolemic patients who were at high cardiovascular (CV) risk, had an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia (HeFH), and/or a history of intolerance to two or more statins, including one at the lowest dose. The trials evaluated two distinct dosing regimens: 150 mg every two weeks or 75 mg every two weeks increasing to 150 mg if needed to reach protocol-specified LDL-C targets. In the trials that used an individualized approach with 75 mg and 150 mg doses, the majority of patients reached their LDL-C goals while remaining on the 75 mg dose. The 75 mg and the 150 mg doses were delivered with a single, self-administered one-milliliter (mL) injection. A summary of primary efficacy endpoints and most common adverse events (AEs) are as follows:

Study	Patient group	Primary efficacy endpoint (percent change from baseline in LDL-C at 24 weeks)		Most common AEs[a]
		Praluent	Comparator	
LONG TERM Praluent (n =1,553) vs. placebo (n =788) 150 mg dose	All patients (high CV risk) (total n=2,341)	61% reduction	1% increase (placebo)[b]	Nasopharyngitis, upper respiratory tract infection, injection site reactions, influenza, diarrhea, urinary tract infection, bronchitis, myalgia, headache, back pain, arthralgia
	- HeFH subgroup (n=415)	56% reduction	7% increase (placebo)[c]	
	- Non-HeFH subgroup (n=1,926)	62% reduction	0.5% reduction (placebo)[d]	
COMBO I Praluent (n =209) vs. placebo (n =107) 75 mg/150 mg dose	High CV risk	48% reduction	2% reduction (placebo)[b]	Upper respiratory tract infection, nasopharyngitis, urinary tract infection, dizziness, sinusitis, injection-site reaction
COMBO II Praluent (n =479) vs. ezetimibe (n =241)	High CV risk	51% reduction	21% reduction (ezetimibe)[b]	Upper respiratory tract infection, accidental overdose,

				dizziness, myalgia
75 mg/150 mg dose OPTIONS I [Baseline statin = atorvastatin 20/40 mg] Praluent (n =104) vs. ezetimibe (n =102) or double atorvastatin (n =104) or switch to rosuvastatin[e] (n =45) 75 mg / 150 mg dose	High CV risk	44% - 54% reduction	• 21% - 23% reduction (ezetimibe)[f] • 5% reduction (double statin dose)[b] • 21% reduction (statin switch)[b]	Nasopharyngitis, upper respiratory tract infection, hypertension, back pain

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(continued)

Study	Patient group	Primary efficacy endpoint (percent change from baseline in LDL-C at 24 weeks)		Most common AEs[a]
		Praluent	Comparator	
OPTIONS II [Baseline statin = rosuvastatin 10/20 mg] Praluent (n =103) vs. ezetimibe (n =101) or double rosuvastatin (n =101) 75 mg / 150 mg dose	High CV risk	36% - 51% reduction	• 11% -14% reduction (ezetimibe)[g] • 16% reduction (statin switch)[g]	Nasopharyngitis, upper respiratory tract infection, hypertension, back pain
ALTERNATIVE Praluent (n =126) vs. ezetimibe (n =125) [Validation arm = atorvastatin 20 mg (n =63)]	High CV risk and history of intolerance to two or more statins	45% reduction	15% reduction (ezetimibe)[b]	Myalgia, nasopharyngitis, arthralgia, upper respiratory tract infection, headache, fatigue
75 mg / 150 mg dose HIGH FH Praluent (n =72) vs. placebo (n =35)	HeFH	46% reduction	7% reduction (placebo)[b]	Nasopharyngitis, injection-site reaction, diarrhea, sinusitis, bronchitis, headache, fatigue
150 mg dose FH I Praluent (n =323) vs. placebo (n =163)	HeFH	49% reduction	9% increase (placebo)[b]	Injection site reactions, nasopharyngitis, influenza, headache
75 mg / 150 mg dose FH II Praluent (n =167) vs. placebo (n =82)	HeFH	49% reduction	3% increase (placebo)[b]	
75 mg / 150 mg dose MONO Praluent (n =52) vs. ezetimibe (n =51)	Moderate CV risk	48% reduction	16% reduction (ezetimibe)[b]	Nasopharyngitis, influenza, upper respiratory tract infection
75 mg/150 mg dose				

a.Occurred in at least 5% of Praluent-treated patients. Rare allergic reactions have also been reported.
b.$p<0.0001$
c.95% confidence interval of the least squares (LS) mean difference vs. placebo: 57.5% - 69% reduction
d.95% confidence interval of the LS mean difference vs. placebo: 59% - 64% reduction

e.45 patients on atorvastatin 40 mg starting dose switched to rosuvastatin 40 mg
f.For patients on atorvastatin 20 mg starting dose p=0.0004; for patients on atorvastatin 40 mg starting dose p<0.0001
g.For patients on rosuvastatin 10 mg starting dose p<0.0001; patients on rosuvastatin 20 mg starting dose did not reach statistical significance

The ODYSSEY ALTERNATIVE trial reassessed statin intolerance, as measured by skeletal muscle AEs, by including a validation arm (atorvastatin 20 mg). Although the trial was not designed to demonstrate differences in AEs between treatment groups, in this trial, there were fewer skeletal muscle AEs in the Praluent group compared to patients treated with atorvastatin (32.5% versus 46%, hazard ratio = 0.61; nominal p value = 0.042), and fewer compared to ezetimibe (41%). In addition, there were numerically fewer discontinuations for skeletal muscle AEs in the Praluent group (Praluent 16%, ezetimibe 20%, atorvastatin 22%). In comparison, the overall rate of discontinuations for skeletal muscle AEs across the Phase 2 and 3 Praluent placebo-controlled studies, where the majority of patients were also on statins, was 0.4% for Praluent (n =2,476) and 0.5% for placebo (n = 1,276).

In January 2015, we and Sanofi announced that the ODYSSEY CHOICE I and ODYSSEY CHOICE II studies met their primary efficacy endpoints. The trials compared the reduction from baseline in LDL-C at 24 weeks with Praluent versus placebo in patients with hypercholesterolemia. In these trials dosing every four weeks, the mean percent reduction in LDL-C from baseline was

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consistent with that seen in previous Phase 3 trials evaluating Praluent in every other week dosing. The most common AEs in the trials (occurring in at least 5% of Praluent-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue. Injection site reactions occurred more frequently in the Praluent groups compared to placebo. Detailed data were presented at the American College of Cardiology (ACC) conference in March 2015.

In March 2015, 18-month (78-week) results of the ODYSSEY LONG TERM Phase 3 trial of Praluent were published online in The New England Journal of Medicine. In the ODYSSEY LONG TERM trial, Praluent 150 mg every two weeks reduced LDL-C by an additional 62% at week 24 when compared to placebo, with consistent LDL-C lowering maintained over 78 weeks. Patients received 78 weeks of treatment followed by an eight-week safety assessment. Patients self-administered a subcutaneous injection every two weeks via a pre-filled syringe. Key results included:

- Efficacy remained consistent throughout treatment, and, at week 78 there was a 56% reduction from baseline in LDL-C for Praluent versus placebo ($p<0.001$).
- At week 24, 81% of patients in the Praluent group achieved their pre-specified LDL-C goal (either 70 mg/dL or 100 mg/dL depending on baseline CV risk) compared to 8.5% for placebo ($p<0.001$).
- AEs occurred in 81% of Praluent and 83% of placebo patients, leading to discontinuation in 7.2% and 5.8% of patients, respectively. AEs were similar between groups, apart from differences in injection site reactions (5.9% Praluent, 4.2% placebo), myalgia (5.4% Praluent, 2.9% placebo), neurocognitive events (1.2% Praluent, 0.5% placebo), and ophthalmological events (2.9% Praluent, 1.9% placebo). In a 3,752-patient, pooled safety analysis of nine placebo-controlled Praluent studies, rates of skeletal muscle-related (15.1% Praluent, 15.4% placebo) and neurocognitive events (0.8% Praluent, 0.7% placebo) were generally balanced between Praluent and placebo.
- At week 78, positively adjudicated pre-specified CV AEs (including additional CV AEs beyond those in the pre-specified ODYSSEY OUTCOMES endpoint of 'major adverse cardiac events' described below) occurred in 4.6% and 5.1% of Praluent and placebo patients, respectively. CV AEs are defined as CHD death including unknown cause, non-fatal myocardial infarction (MI), fatal and non-fatal ischemic stroke, unstable angina requiring hospitalization, congestive heart failure requiring hospitalization and ischemia-driven coronary revascularization procedure.
- In a post hoc analysis using a pre-specified endpoint from the ODYSSEY OUTCOMES study that included CHD death, MI, stroke, or unstable angina requiring hospitalization, a lower rate of adjudicated major adverse cardiac events was observed in the Praluent group (27 of 1,550 patients, 1.7%) compared with the placebo group (26 of 788 patients, 3.3%; hazard ratio 0.52; 95% percent confidence interval (CI), 0.31 to 0.90; nominal $p<0.01$). The cumulative incidence curves diverged progressively over time.
- ODYSSEY LONG TERM was not designed to evaluate CV outcomes. The number of CV events seen in the post hoc analysis was relatively small, which limits the ability to draw conclusions on the effects of Praluent on CV events. The ongoing ODYSSEY OUTCOMES trial will evaluate the CV benefits of Praluent.

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 SARIL-RA-MOBILITY Trial. In 2013, we and Sanofi announced that in the 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. The 52 week SARIL-RA-MOBILITY Phase 3 trial enrolled approximately 1,200 patients with active, moderate-to-severe rheumatoid arthritis, and who were inadequate responders to MTX therapy. Patients were randomized to one of three subcutaneous treatment groups, all in combination with MTX and dosed every other week: sarilumab 200 mg, sarilumab 150 mg, or placebo. Both sarilumab groups showed clinically relevant and statistically significant improvements compared to the placebo group in all three co-primary endpoints ($p<0.0001$).

Additional Phase 3 Studies. We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-ONE, SARIL-RA-MONARCH, SARIL-RA-EASY, and SARIL-RA-KAKEHASI (in Japan). In addition, the SARIL-RA-HARUKA long-term safety trial was initiated in Japan in the first quarter of 2015. SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, SARIL-RA-ONE, and SARIL-RA-EASY are fully enrolled. 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 (TNF-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.

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Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. A Phase 2 study, SARIL-NIU-SATURN, was initiated in 2013 and is a placebo-controlled proof-of-concept study evaluating the safety and efficacy of sarilumab in non-infectious uveitis.

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, chronic sinusitis with nasal polyposis, 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 2b Trial. In July 2014, we and Sanofi announced positive results from a Phase 2b dose-ranging study of dupilumab in adult patients with moderate-to-severe atopic dermatitis. All doses of dupilumab met the primary endpoint of a greater improvement in Eczema Severe Score Index (EASI) scores from baseline compared to placebo. In the Phase 2b trial, all five subcutaneous doses of dupilumab showed a dose-dependent improvement in the primary endpoint, the mean percent change in EASI score from baseline to week 16. The improvements in EASI score ranged from a high of 74% for patients in the highest dose group, who received 300 mg weekly, to a low of 45% in patients who received the lowest dose of 100 mg monthly, compared to 18% for patients in the placebo group ($p<0.0001$ for all doses). The most common AE in the Phase 2b study was nasopharyngitis, which was balanced across dupilumab treatment groups (18.5% to 23%) compared to placebo (21%). Injection site reactions were more frequent in the dupilumab group (5% to 9.5%) compared to placebo (3%), as was headache (12% to 15%) compared to placebo (8%). Dupilumab-treated patients showed highly statistically significant and dose-dependent improvements in additional key efficacy measures compared to placebo after 16 weeks of treatment:

- 12% to 33% of dupilumab-treated patients achieved clearing or near-clearing of skin lesions, as measured by an Investigator's Global Assessment (IGA) score of 0 or 1, compared to 2% with placebo ($p=0.02$ to $p<0.0001$).
- Dupilumab-treated patients experienced a 16.5% to 47% mean reduction in itching, as measured by the pruritus numerical-rating scale (NRS) score, compared to an increase of 5% in the placebo group ($p=0.0005$ to $p<0.0001$).

This Phase 2b double-blind, placebo-controlled, 16-week, dose-ranging study randomized 380 patients with moderate-to-severe atopic dermatitis, who could not be adequately controlled with topical medication or for whom topical treatment was not advisable. Patients were randomized to receive one of five doses of dupilumab (300 mg weekly, 300 mg every other week, 300 mg monthly, 200 mg every other week, 100 mg monthly) or placebo. Patients in the study had approximately 50% of their skin affected by atopic dermatitis at baseline. In the year preceding enrollment in the study, approximately 35% of patients received an oral corticosteroid and approximately 20% received a systemic non-steroid immunosuppressant for atopic dermatitis. Approximately 60% of patients had another allergic condition, including approximately 40% of patients who had a history of asthma. The follow-up period of the study is ongoing and patients will be followed for 16 weeks after treatment.

Phase 3 Study. In the fourth quarter of 2014, four Phase 3 trials in atopic dermatitis, LIBERTY AD CHRONOS, LIBERTY AD SOLO 1, LIBERTY AD SOLO 2, and LIBERTY AD Open label Extension, were initiated and are currently enrolling patients. LIBERTY AD CHRONOS is a randomized, double-blind, placebo-controlled, multi-national study with the primary objective of demonstrating the efficacy of dupilumab in adults with moderate-to-severe atopic dermatitis when administered concomitantly with topical corticosteroids through 16 weeks. Secondary objectives of the LIBERTY AD CHRONOS trial will evaluate the long-term safety and efficacy of dupilumab up to 52 weeks. The LIBERTY AD Phase 3 clinical program will consist of patients with moderate-to-severe atopic dermatitis at sites worldwide.

In November 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, and the determination that atopic dermatitis is a serious disease and preliminary clinical evidence indicates that

the drug may demonstrate substantial improvement over existing therapies.

Phase 2 Trial in Adolescents and Children. In March 2015, a Phase 2 pharmacokinetic and safety study in adolescents and children (6-17 years of age) with moderate-to-severe atopic dermatitis was initiated.

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Asthma

Phase 2b Study. In 2014, we and Sanofi announced positive results from the interim analysis of a dose-ranging Phase 2b study of dupilumab in adult patients with uncontrolled persistent asthma. In the study, the three highest doses of dupilumab in combination with standard-of-care therapy met the primary endpoint of a statistically significant improvement from baseline in FEV_1 at 12 weeks in patients with high blood eosinophils (greater than or equal to 300 cells/microliter), as compared to placebo in combination with standard-of-care therapy. In addition, two doses of dupilumab (200 mg every other week and 300 mg every other week) showed a statistically significant improvement in mean percent change in FEV_1, as well as a reduction in severe exacerbations, in both the high eosinophils and overall study population. Key results included:

- In the high eosinophils patient group - mean improvements from baseline in FEV_1 (and mean percent change in FEV_1) at 12 weeks, the primary (and a secondary) endpoint of the study were: 390 ml (26%) dupilumab 300 mg every other week (Q2W); 430 ml (26%) dupilumab 200 mg Q2W; 180 ml (10%) placebo. ($p<0.01$)
- In the overall population - mean improvements from baseline in FEV_1 at 12 weeks (and mean percent change in FEV_1) were: 280 ml (18%) dupilumab 300 mg Q2W; 310 ml (18%) dupilumab 200 mg Q2W; 120 ml (6%) placebo. ($p<0.001$)
- In both the high eosinophils patient group and overall patient group - dupilumab showed a reduction in adjusted annualized rate of severe exacerbations compared to placebo (64% to 75% reduction, $p<0.05$ for high eosinophils group and $p < 0.01$ for the overall population)

These results were based on a pre-specified interim analysis, which occurred when all patients had reached week 12 of the 24-week treatment period; the average treatment duration at the time of the analysis was 21.5 weeks. The final analyses on exacerbations and safety will occur at 24 weeks. The most common AE was injection site reaction, which was more frequent in the four dupilumab dose groups (13% to 25%) compared to placebo (12%). Other common AEs in the study included upper respiratory tract infection (10% to 13% dupilumab; 13% placebo), headache (5% to 10% dupilumab; 8% placebo), nasopharyngitis (3% to 10% dupilumab; 6% placebo) and bronchitis (5% to 8% dupilumab; 8% placebo). The incidence of infections was balanced across treatment groups (42% to 45% dupilumab; 46% placebo), as was the incidence of serious AEs (3% to 7% dupilumab; 5% placebo).

The double-blind, placebo-controlled, 24-week, dose-ranging study enrolled 776 adult patients with uncontrolled persistent asthma, as defined by the Global Initiative for Asthma 2014 Guidelines. Trial participants were randomized to receive one of four doses of dupilumab (300 mg every other week, 200 mg every other week, 300 mg monthly, 200 mg monthly) or placebo. Approximately 40 percent of patients had high eosinophils across the dose groups. During the treatment period, patients continue their stable medium- or high-dose inhaled corticosteroid and long-acting beta agonist (ICS/LABA) combination product. Patients can administer inhaled rescue medication as needed during the study. A severe exacerbation event during the study is defined as a deterioration of asthma requiring the use of systemic corticosteroids for three or more days, or hospitalization or an emergency room visit. Approximately 77% of randomized patients have a history of atopic disease, which includes atopic dermatitis, allergic conjunctivitis, allergic rhinitis, chronic rhinosinusitis, nasal polyposis, food allergy, and/or hives history.

The 24-week treatment period of the study is ongoing, and patients will be followed for 16 weeks after treatment. Full results of the trial will be presented at the upcoming American Thoracic Society meeting.

Phase 3 Study. A Phase 3 study in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015.

Nasal Polyps in Patients With Chronic Sinusitis

Phase 2 Trial. In 2013, a Phase 2 trial in NPwCS was initiated. In September 2014, we and Sanofi announced positive results from the Phase 2 proof-of-concept study of dupilumab in patients with moderate-to-severe NPwCS who did not respond to intranasal corticosteroids. The randomized, double-blind, placebo-controlled study enrolled 60 adult patients with moderate-to-severe NPwCS. Patients in the study received 300 mg of dupilumab or placebo administered once per week subcutaneously for 16 weeks, following an initial loading dose of 600 mg. All patients in the study also received a standard-of-care nasal corticosteroid spray. Patients were eligible for the study if they continued to have severe NPwCS despite standard treatment for at least one month. Fifty percent of patients in the study had received prior surgery for their condition. Asthma was also present in 58 percent of NPwCS patients in the

study. The conditions are often co-morbid and symptoms/exacerbations are frequently interdependent.

In the study, dupilumab resulted in a statistically-significant improvement in the size of nasal polyps, as measured by endoscopic Nasal Polyp Score (NPS), the primary endpoint of the study. Statistically significant improvements in all secondary efficacy endpoints were also observed, including objective measures of sinusitis by CT scan, nasal air flow, and patient-reported symptoms (sense of smell, congestion, postnasal drip, runny nose and sleep disturbance). In a pre-specified exploratory analysis, dupilumab-treated patients who also had asthma demonstrated significant improvements in asthma control. The safety profile was consistent with previous studies. The most common AEs with dupilumab were injection site reactions, nasopharyngitis, oropharyngeal pain, epistaxis, headache, and dizziness. Detailed results of the study will be presented at an upcoming medical conference.

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Eosinophilic Esophagitis

Phase 2 Study. A Phase 2 study 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.

Research Programs

Our preclinical research programs are in the areas of oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Research and Development Technologies

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate EYLEA, ZALTRAP, and ARCALYST. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region," resulting in high affinity product candidates. VelociSuite is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuite. VelociSuite consists of VelocImmune, VelociGene, VelociMouse®, and VelociMab. The VelocImmune mouse platform is utilized to produce fully human monoclonal antibodies. VelocImmune was generated by exploiting our VelociGene technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. VelocImmune mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. VelocImmune and our entire VelociSuite offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the VelocImmune technology to produce our next generation of drug candidates for preclinical and clinical development.

Our VelociGene platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, VelociGene offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, VelociGene allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our VelociMouse technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our VelociMouse technology are suitable for direct

phenotyping or other studies. We have also developed our VelociMab platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our VelocImmune human monoclonal antibodies. We have utilized our VelociSuite technologies to develop a class of potential drug candidates, known as bi-specific antibodies. In the area of immunotherapies in oncology, we are exploring the use of bi-specific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. Our first such bi-specific antibody, which entered into clinical development in 2014, targets CD20 and CD3.

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Regeneron Genetics Center. In 2014, we launched a new human genetics initiative via a wholly owned subsidiary, Regeneron Genetics Center LLC. RGC leverages de-identified clinical and molecular data from human volunteers for medically relevant associations in a blinded fashion designed to preserve patients' privacy. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process. RGC is undertaking both large population-based efforts as well as family- and founder-based approaches. RGC utilizes laboratory automation and an innovative approach to cloud computing to achieve high-quality throughput at a rate that exceeds 70,000 unique samples per year.

Central to the work of RGC is a collaboration with the Geisinger Health System of Pennsylvania. During the initial five-year collaboration term, Geisinger plans to collect samples from more than 100,000 consented patient volunteers, while RGC will perform sequencing and genotyping to generate de-identified genomic data. RGC has expanded on its foundational population-based collaboration with Geisinger with new partners with other institutions such as Columbia University Medical Center, the Clinic for Special Children, Baylor College of Medicine, and SickKids in Toronto.

Collaboration Agreements

Collaborations with Sanofi

ZALTRAP. Since September 2003, we and Sanofi have been parties to a global collaboration (ZALTRAP Collaboration Agreement) for the development and commercialization of ZALTRAP. In February 2015, we and Sanofi entered into an Amended ZALTRAP Agreement. Under the terms of the Amended ZALTRAP Agreement, Sanofi will be solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. We will also be paid for all quantities of ZALTRAP manufactured by us pursuant to a supply agreement through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation (which was approximately $461 million at December 31, 2014) to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement.

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 and a License and Collaboration Agreement (each as amended). Pursuant to the collaboration, Sanofi is funding up to $160 million per year of our antibody discovery activities over the period from 2010-2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified through discovery research under the discovery agreement, Sanofi has the option to license rights to the candidate under the license 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 up front, 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. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

Under our collaboration agreement, Sanofi will record 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. 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 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.

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Collaborations with Bayer HealthCare

EYLEA outside the United States. Since October 2006, we and Bayer HealthCare 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 HealthCare collaborate on, and share the costs of, the development of EYLEA through an integrated global plan. Bayer HealthCare 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.

Since inception of the agreement, we have earned $110.0 million of development milestone payments and $165.0 million of sales milestone payments from Bayer HealthCare. During the first quarter of 2015, we earned the final potential milestone payment under our Bayer HealthCare collaboration agreement in connection with EYLEA outside the United States.

Commencing with the first commercial sale of EYLEA in a major market country outside the United States, we became obligated to reimburse Bayer HealthCare 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 HealthCare at a faster rate. As a result, we expect that, initially, a portion of our share of EYLEA profits outside the United States will be used to reimburse Bayer HealthCare for this repayment obligation.

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

PDGFR-beta antibody outside the United States. In January 2014, we entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, 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 HealthCare 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 HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, and 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 HealthCare 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. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to us in the first quarter of 2014. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to $15.0 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

If Bayer HealthCare 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.

Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. If Bayer HealthCare does not opt-in to the collaboration, we will have exclusive rights to develop and commercialize PDGFR-beta antibodies (except as a combination product with EYLEA) for use outside the United States.

We also have the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If we opt-out of the collaboration and Bayer HealthCare exercises its right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination product with EYLEA) outside of the United States, be responsible for all development costs outside of the United

States, be responsible for all royalty and milestone payments to a third party, and will retain all of the profits from sales of the PDGFR-beta antibody outside of the United States.

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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, will expand and require additional resources. We also expect to incur substantial costs related to the 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 operating 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, and the continuation of our collaborations with Sanofi and Bayer HealthCare, 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. 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 2015 to date were, and plans for the next twelve months are, as follows:

Trap-based Clinical Programs:

	2015 Events to Date	2015-2016 Plans (next 12 months)
EYLEA		
	Bayer HealthCare received regulatory approval for EYLEA in certain countries for the treatment of patients with wet AMD, macular edema secondary to CRVO, and DME, and continued to pursue regulatory applications for marketing approval in additional countries	Bayer HealthCare to file for additional ex-US regulatory approvals for various indications
		Regulatory agency decisions on applications outside the United States for various indications
	European Commission approved EYLEA for the treatment of macular edema secondary to BRVO	We and Bayer HealthCare to report 3-year data from Phase 3 DME trials
	Bayer HeathCare submitted marketing authorization application to EMA for the treatment of mCNV	
	FDA approved EYLEA for the treatment of diabetic retinopathy in patients with DME	

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Antibody-based Clinical Programs:

	2015 Events to Date	2015-2016 Plans (next 12 months)
Praluent (PCSK9 Antibody)	BLA accepted for priority review in the United States Regulatory application accepted for review by the EMA Reported positive results from ODYSSEY CHOICE I and CHOICE II trials ODYSSEY LONG TERM 18-month trial results published in The New England Journal of Medicine	Continue enrollment of Phase 3 ODYSSEY OUTCOMES trial Report additional results from Phase 3 ODYSSEY trials File for additional regulatory approvals outside the United States FDA and EMA decisions on regulatory applications
Sarilumab (IL-6R Antibody)	Initiated Phase 3 MONARCH study (head-to-head monotherapy study against adalimumab) Initiated Phase 3 HARUKA study in Japan	Continue enrollment in Phase 3 SARIL-RA program Complete patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis Report results from additional Phase 3 trials Submit for regulatory approval in the United States
Dupilumab (IL-4R Antibody)	Initiated Phase 2 study in EoE Initiated Phase 2 study in atopic dermatitis in adolescents and children Initiated Phase 3 study in asthma	Continue patient enrollment in various Phase 2 and Phase 3 studies Initiate Phase 3 study in NPwCS
REGN1033 (GDF8 Antibody)	Phase 2 proof-of-concept study in elderly men and women with sarcopenia met its primary endpoint, while secondary, functional endpoints were mixed.	Determine future development plan
REGN1908-1909 (target not disclosed)		Continue patient enrollment in Phase 2 study
REGN1500 (Angptl-3 Antibody)	Initiated Phase 2 study On partial clinical hold by the FDA	Complete patient enrollment in Phase 1 and Phase 2 studies
REGN2176-3 (PDGFR-beta Antibody in combination with EYLEA)	Received Fast Track designation from the FDA for the treatment of patients with wet AMD Initiated Phase 2 study	Continue patient enrollment in Phase 2 study
REGN1400 (ErbB3 Antibody)		Determine future development plan
REGN1154 (target not disclosed)		Determine future development plan
REGN1193 (target not disclosed)	Continued patient enrollment in Phase 1 study	Complete patient enrollment in Phase 1 study
REGN2222 (RSV)	Completed patient enrollment in Phase 1 study	Initiate pivotal study

REGN1979 (CD20 and CD3 Antibody)	Continued patient enrollment in Phase 1 study	Complete patient enrollment in Phase 1 study
REGN910-3 (Ang2 Antibody co-formulated with EYLEA)	Completed patient enrollment in Phase 1 study	
REGN2810 (PD-1 Antibody)	Initiated Phase 1 study	Continue patient enrollment in Phase 1 study
Fasinumab (NGF Antibody)	On partial clinical hold by the FDA	Re-enter clinical development

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Results of Operations

The results of operations discussion below reflects certain revisions to previously-issued financial statements. See Note 4 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

Three Months Ended March 31, 2015 and 2014

Net Income

Net income for the three months ended March 31, 2015 and 2014 consists of the following:

(In millions)	2015	2014
Revenues	$869.6	$625.7
Operating expenses	(586.1)	(434.2)
Other income (expense)	(7.0)	(10.6)
Income before income taxes	276.5	180.9
Income tax expense	(200.5)	(112.6)
Net income	$76.0	$68.3

Revenues

Revenues for the three months ended March 31, 2015 and 2014 consist of the following:

(In millions)	2015	2014
Net product sales	$544.6	$362.4
Collaboration revenue:		
Sanofi	173.4	130.5
Bayer HealthCare	123.8	125.3
Total collaboration revenue	297.2	255.8
Technology licensing and other revenue	27.8	7.5
Total revenues	$869.6	$625.7

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 July 2014, macular edema following BRVO in October 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended March 31, 2015, EYLEA net product sales increased to $541.1 million from $359.0 million for the three months ended March 31, 2014 due to higher sales volume. For the three months ended March 31, 2015 and 2014, we also recognized ARCALYST net product sales of $3.5 million and $3.4 million, respectively.

For the three months ended March 31, 2015 and 2014, we recorded 69% and 79%, 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, 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
Balance as of December 31, 2013	$4.4	$19.7	$0.5	$24.6
Provision related to current period sales	6.9	16.9	0.4	24.2
Credits/payments	(6.7)	(16.3)	(0.4)	(23.4)
Balance as of March 31, 2014	$4.6	$20.3	$0.5	$25.4

Sanofi Collaboration Revenue

The collaboration revenue we earned from Sanofi, as detailed below, primarily consisted of (i) recognition of previously deferred revenue related to our ZALTRAP Collaboration Agreement, and (ii) reimbursement for research and development expenses that we incurred, partly offset by sharing of pre-launch commercialization expenses, in connection with the companies' antibody collaboration.

Sanofi Collaboration Revenue	Three Months Ended March 31,	
(In millions)	2015	2014
ZALTRAP:		
Regeneron's share of losses in connection with commercialization of ZALTRAP	—	$(3.2)
Reimbursement of Regeneron research and development expenses	$0.7	1.1
Other	15.2	2.2
Total ZALTRAP	15.9	0.1
Antibody:		
Reimbursement of Regeneron research and development expenses	168.8	126.8
Reimbursement of Regeneron commercialization-related expenses	8.5	—
Regeneron's share of losses in connection with commercialization of antibodies	(22.4)	—
Other	2.6	3.6
Total Antibody	157.5	130.4
Total Sanofi collaboration revenue	$173.4	$130.5

In September 2003, we and Sanofi entered into a ZALTRAP Collaboration Agreement to jointly develop and commercialize ZALTRAP. Under the terms of ZALTRAP Collaboration Agreement, we and Sanofi shared profits and losses on sales of ZALTRAP outside of Japan, and we were entitled to receive a percentage of sales of ZALTRAP in Japan. Our share of the loss in connection with the commercialization of ZALTRAP in the first quarter of 2014 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales.

As described above under "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP", in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement. As a result, in the first quarter of 2015 we recognized $14.9 million of previously deferred revenue under the ZALTRAP Collaboration

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Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since our risk of inventory loss under the collaboration no longer exists, and (ii) the unamortized portion of up-front payments from Sanofi as we have no further performance obligations.

In the first quarter of 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of $46.0 million under our discovery agreement and $122.8 million under our license agreement, compared to $40.2 million and $86.6 million, respectively, in the first quarter 2014. The higher reimbursement of development costs in the first quarter of 2015, compared to the same period in 2014, was primarily due to increased development activities for Praluent (including manufacturing pre-launch commercial supplies), dupilumab, and REGN1033.

Effective in the second and fourth quarters of 2014, we and Sanofi began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' antibody collaboration agreement. Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize these antibody product candidates. In addition, we began recording our share of losses in connection with commercialization of these two antibody product candidates.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of March 31, 2015, $62.6 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

Bayer HealthCare Collaboration Revenue

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

Bayer HealthCare Collaboration Revenue	Three Months Ended March 31,	
(In millions)	2015	2014
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$89.4	$61.2
Sales milestones	15.0	30.0
Cost-sharing of Regeneron EYLEA development expenses	2.7	20.3
Other	12.9	10.9
Total EYLEA	120.0	122.4
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	1.3	0.5
Other	2.5	2.4
Total PDGFR-beta antibody	3.8	2.9
Total Bayer HealthCare collaboration revenue	$123.8	$125.3

Bayer HealthCare commenced sales of EYLEA outside the United States for the treatment of wet AMD in 2012, macular edema secondary to CRVO in 2013, visual impairment due to DME in the third quarter of 2014, and mCNV (in Japan) in the fourth quarter of 2014. In addition, in February 2015, the European Commission approved EYLEA for the treatment of macular edema following RVO, which includes macular edema following BRVO. Regeneron's net profit in connection with commercialization of EYLEA outside the United States is summarized below.

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Regeneron's Net Profit from EYLEA Sales Outside the United States	Three Months Ended March 31,	
(In millions)	2015	2014
Net product sales outside the United States	$291.8	$218.1
Regeneron's share of collaboration profit from sales outside the United States	103.4	75.6
Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation	(14.0)	(14.4)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$89.4	$61.2

Bayer HealthCare records revenue from sales of EYLEA outside the United States. Bayer HealthCare provides us with an estimate of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In the first quarter of 2015 and 2014, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer HealthCare for a portion of the agreed-upon development expenses previously incurred by Bayer HealthCare.

In the first quarter of 2015, we earned a $15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. In the first quarter of 2014, we earned two $15.0 million sales milestones from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million and $600 million, respectively, over a twelve-month period.

Cost-sharing of our global EYLEA development expenses with Bayer HealthCare decreased in the first quarter of 2015 compared to the same period in 2014. In January 2014, Bayer HealthCare decided to participate in the global development and commercialization of EYLEA outside the United States for the treatment of macular edema following BRVO. In connection with this decision, Bayer HealthCare reimbursed us $15.7 million for a defined share of the EYLEA global development costs that we had incurred prior to February 2014 for the BRVO indication, which was recognized as Bayer HealthCare collaboration revenue in the first quarter of 2014. In addition, all future agreed upon global EYLEA development expenses incurred in connection with BRVO are being shared equally, and any future profits or losses on sales of EYLEA outside of the United States for the treatment of macular edema following BRVO are also shared (for countries other than Japan). We are entitled to receive a tiered percentage of EYLEA net sales in Japan.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States. In addition, other EYLEA revenue includes reimbursements for producing EYLEA commercial supplies for Bayer HealthCare, and recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of March 31, 2015, $13.1 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration Agreements - Collaborations with Bayer HealthCare - PDGFR-beta antibody outside the United States." Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front payment and non-substantive milestones received in the first quarter of 2014. As of March 31, 2015, $17.3 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Technology Licensing and Other Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first quarter of both 2015 and 2014, we

recognized $5.9 million of revenue related to this agreement. As of March 31, 2015, $75.1 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

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In connection with the February 2015 Amended ZALTRAP Agreement with Sanofi, we recorded $19.8 million of revenue primarily related to (i) manufacturing ZALTRAP commercial supplies for Sanofi and (ii) a percentage of net sales of ZALTRAP for the period from July 1, 2014 through March 31, 2015.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris (canakinumab). In the first quarter of 2015 and 2014, technology licensing and other revenue included $2.1 million and $1.6 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $586.1 million in the first quarter of 2015 from $434.2 million in the first quarter of 2014. Our average headcount in the first quarter of 2015 increased to 3,066 from 2,389 in the same period in 2014, principally in connection with expanding our research and development and commercialization activities.

Operating expenses in the first quarter of 2015 and 2014 included a total of $103.8 million and $75.8 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense). The increase in total Non-cash Compensation Expense in the first quarter of 2015 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2014 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $343.1 million in the first quarter of 2015 from $287.4 million in the same period of 2014. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses* (In millions)	Three Months Ended March 31, 2015	2014	Increase (Decrease)
Payroll and benefits [1]	$116.1	$96.0	$20.1
Clinical trial expenses	56.2	48.2	8.0
Clinical manufacturing costs [2]	88.8	58.2	30.6
Research and other development costs	25.9	27.8	(1.9)
Occupancy and other operating costs	29.2	27.4	1.8
Cost-sharing of Bayer HealthCare and Sanofi development expenses [3]	26.9	29.8	(2.9)
Total research and development expenses	$343.1	$287.4	$55.7

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

[1] Includes Non-cash Compensation Expense of $50.2 million for the three months ended March 31, 2015 and $37.6 million for the three months ended March 31, 2014.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Also includes Non-cash Compensation Expense of $9.3 million for the three months ended March 31, 2015 and $5.7 million for the three months ended March 31, 2014.

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

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to additional costs for clinical studies of dupilumab and early-

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stage antibody product candidates, partly offset by lower Praluent- and EYLEA-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of Praluent. Cost-sharing of Bayer HealthCare and Sanofi development expenses primarily consists of costs related to our obligation to fund 20% of Sanofi's Phase 3 Praluent and sarilumab development costs, which commenced during the fourth quarter of 2013. We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaborations with Bayer HealthCare and Sanofi, the portion of Bayer HealthCare and Sanofi's development expenses which they incur and we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	Three Months Ended March 31,		Increase
(In millions)	2015	2014	(Decrease)
Praluent	$81.6	$53.5	$28.1
Dupilumab	54.6		