REGENERON PHARMACEUTICALS INC
Form 10-Q
August 04, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2016

OR

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

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

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

(914) 847-7000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes X No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes X No

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

Large accelerated filer X		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes No X

Number of shares outstanding of each of the registrant's classes of common stock as of July 14, 2016:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,911,456
Common Stock, $.001 par value	103,383,050

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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)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$646,508	$809,102
Marketable securities	398,656	236,121
Accounts receivable - trade, net	1,431,966	1,152,489
Accounts receivable from Sanofi	138,067	153,152
Accounts receivable from Bayer	181,938	162,152
Inventories	316,073	238,578
Prepaid expenses and other current assets	96,017	163,501
Total current assets	3,209,225	2,915,095
Marketable securities	589,852	632,162
Property, plant, and equipment, net	1,772,923	1,594,120
Deferred tax assets	626,191	461,945
Other assets	6,715	5,810
Total assets	$6,204,906	$5,609,132
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$759,643	$644,112
Deferred revenue from Sanofi, current portion	104,141	101,573
Deferred revenue - other, current portion	84,084	51,914
Other current liabilities	3,695	13,563
Total current liabilities	951,563	811,162
Deferred revenue from Sanofi	549,342	582,664
Deferred revenue - other	146,449	82,015
Facility lease obligations	361,523	362,919
Other long-term liabilities	119,523	115,535
Total liabilities	2,128,400	1,954,295
Stockholders' equity:		
Preferred stock, $.01 par value; 30,000,000 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, $.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 1,911,456 in 2016 and 1,913,776 in 2015	2	2
Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 107,132,543 in 2016 and 106,378,001 in 2015	107	106
Additional paid-in capital	3,156,942	3,099,526
Retained earnings	1,230,303	852,700

Accumulated other comprehensive income	5,204	8,572
Treasury stock, at cost; 3,761,628 shares in 2016 and 3,642,820 in 2015	(316,052)	(306,069)
Total stockholders' equity	4,076,506	3,654,837
Total liabilities and stockholders' equity	$6,204,906	$5,609,132

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Statements of Operations				
Revenues:				
Net product sales	$834,219	$657,819	$1,618,401	$1,202,392
Sanofi collaboration revenue	163,414	195,110	383,108	368,466
Bayer collaboration revenue	191,896	134,237	371,488	258,083
Other revenue	23,100	11,451	40,481	39,288
	1,212,629	998,617	2,413,478	1,868,229
Expenses:				
Research and development	559,930	390,330	1,030,042	733,443
Selling, general, and administrative	292,038	174,588	581,715	333,579
Cost of goods sold	41,247	60,855	120,189	103,425
Cost of collaboration and contract manufacturing	27,786	27,985	60,596	69,370
	921,001	653,758	1,792,542	1,239,817
Income from operations	291,628	344,859	620,936	628,412
Other income (expense):				
Investment income	2,801	1,653	5,050	1,833
Interest and other expense, net	(2,173)	(18,516)	(3,579)	(25,726)
	628	(16,863)	1,471	(23,893)
Income before income taxes	292,256	327,996	622,407	604,519
Income tax expense	(96,038)	(133,353)	(244,804)	(333,855)
Net income	$196,218	$194,643	$377,603	$270,664
Net income per share - basic	$1.88	$1.89	$3.61	$2.64
Net income per share - diluted	$1.69	$1.69	$3.24	$2.35
Weighted average shares outstanding - basic	104,633	102,886	104,462	102,558
Weighted average shares outstanding - diluted	116,231	115,259	116,617	114,962
Statements of Comprehensive Income				
Net income	$196,218	$194,643	$377,603	$270,664
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net of tax	840	(28,751)	(3,368)	(33,098)
Comprehensive income	$197,058	$165,892	$374,235	$237,566

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)

	Six Months Ended June 30, 2016		2015	
Cash flows from operating activities:				
Net income	$ 377,603		$ 270,664	
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation and amortization	48,006		31,325	
Non-cash compensation expense	273,941		198,016	
Other non-cash charges and expenses, net	7,795		33,017	
Deferred taxes	(162,652	)	(59,069	)
Changes in assets and liabilities:				
Increase in Sanofi, Bayer, and trade accounts receivable	(284,178	)	(418,753	)
Increase in inventories	(72,888	)	(45,591	)
Decrease in prepaid expenses and other assets	57,086		33,842	
Increase (decrease) in deferred revenue	65,850		(16,685	)
Increase in accounts payable, accrued expenses, and other liabilities	133,925		129,338	
Total adjustments	66,885		(114,560	)
Net cash provided by operating activities	444,488		156,104	
Cash flows from investing activities:				
Purchases of marketable securities	(228,942	)	(340,844	)
Sales or maturities of marketable securities	102,177		193,769	
Capital expenditures	(242,930	)	(354,055	)

Net cash used in investing activities	(369,695)	(501,130)
Cash flows from financing activities:		
(Payments) proceeds in connection with facility lease obligations	(1,213)	26,780
Repayments of convertible senior notes	(12,650)	(144,001)
Payments in connection with reduction of outstanding warrants	(242,117)	(124,531)
Proceeds from issuance of Common Stock	63,606	115,825
Payments in connection with Common Stock tendered for employee tax obligations	(45,013)	(35,930)
Excess tax benefit from stock-based compensation	—	248,718
Net cash (used in) provided by financing activities	(237,387)	86,861
Net decrease in cash and cash equivalents	(162,594)	(258,165)
Cash and cash equivalents at beginning of period	809,102	648,719
Cash and cash equivalents at end of period	$ 646,508	$ 390,554

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

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

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2015 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015.

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

2. Product Sales

EYLEA® net product sales in the United States totaled $830.9 million and $654.6 million for the three months ended June 30, 2016 and 2015, respectively, and $1,611.8 million and $1,195.7 million for the six months ended June 30, 2016 and 2015, respectively. In addition, ARCALYST® net product sales totaled $3.3 million and $3.2 million for the three months ended June 30, 2016 and 2015, respectively, and $6.6 million and $6.7 million for the six months ended June 30, 2016 and 2015, respectively.

The Company recorded 56% and 69% for the three months ended June 30, 2016 and 2015, respectively, and 58% and 69% for the six months ended June 30, 2016 and 2015, 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, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the six months ended June 30, 2016 and 2015.

	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2015	$ 6,419	$ 48,313	$ 517	$55,249
Provision related to current period sales	41,326	74,289	12,341	127,956
Credits/payments	(36,110)	(94,467)	(11,782)	(142,359)
Balance as of June 30, 2016	$ 11,635	$ 28,135	$ 1,076	$40,846
Balance as of December 31, 2014	$ 3,083	$ 21,166	$ 532	$24,781
Provision related to current period sales	25,481	54,747	3,454	83,682
Credits/payments	(23,090)	(36,433)	(3,482)	(63,005)
Balance as of June 30, 2015	$ 5,474	$ 39,480	$ 504	$45,458

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

3. Collaboration Agreements

a. Sanofi

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

	Three Months Ended June 30,	
Sanofi Collaboration Revenue	2016	2015
Antibody:		
Reimbursement of Regeneron research and development expenses	$144,232	$211,516
Reimbursement of Regeneron commercialization-related expenses	85,885	27,347
Regeneron's share of losses in connection with commercialization of antibodies	(122,107)	(46,313)
Other	3,054	2,560
Total Antibody	111,064	195,110
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	32,350	—
Other	20,000	—
Total Immuno-oncology	52,350	—
	$163,414	$195,110

	Six Months Ended June 30,	
Sanofi Collaboration Revenue	2016	2015
Antibody:		
Reimbursement of Regeneron research and development expenses	$337,834	$380,336
Reimbursement of Regeneron commercialization-related expenses	159,159	35,805
Regeneron's share of losses in connection with commercialization of antibodies	(221,529)	(68,718)
Other	6,019	5,121
Total Antibody	281,483	352,544
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	61,625	—
Other	40,000	—
Total Immuno-oncology	101,625	—
ZALTRAP:		
Reimbursement of Regeneron research and development expenses	—	686
Other	—	15,236
Total ZALTRAP	—	15,922
	$383,108	$368,466

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Antibodies

In November 2007, the Company entered into a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). The Antibody Collaboration is governed by the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended). Pursuant to the Antibody Discovery Agreement, Sanofi will fund up to $130.0 million of the Company's research activities in each of 2016 and 2017. Under the License and Collaboration Agreement, agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. During the three months ended June 30, 2016 and 2015, the Company recognized as additional research and development expense $30.6 million and $22.5 million, respectively, and during the six months ended June 30, 2016 and 2015, the Company recognized as additional research and development expense $52.3 million and $47.5 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent®, sarilumab, and, commencing in the first quarter of 2016, dupilumab. Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with preparing to commercialize or commercializing, as applicable, Praluent, sarilumab, and, effective in the first quarter of 2016, dupilumab.

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

Immuno-Oncology

In July 2015, the Company and Sanofi entered into a collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement ("IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). Pursuant to the IO Discovery Agreement, Sanofi will reimburse the Company for up to $150.0 million in 2016 to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Under the terms of the IO License and Collaboration Agreement, the parties are co-developing the Company's antibody product candidate targeting the receptor known as programmed cell death protein 1, or PD-1 ("REGN2810"). The parties share equally, on an ongoing basis, development expenses for REGN2810.

The $640.0 million in aggregate up-front payments made by Sanofi during 2015 in connection with the execution of the IO Collaboration has been recorded by the Company as deferred revenue, and is being recognized ratably as revenue over the related performance period.

ZALTRAP

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"). Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all

development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi pays the Company a percentage of aggregate net sales of ZALTRAP during each calendar year.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015, the Company recognized $14.9 million of collaboration revenue, which was previously recorded as deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since the risk of inventory loss no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as the Company had no further performance obligations. In addition, during the three months ended June 30, 2016 and 2015, the Company recorded $9.3 million and $3.2 million, respectively, and during the six months ended June 30, 2016 and 2015, the Company recorded $14.6

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million and $23.0 million, respectively, in other revenue primarily related to a percentage of net sales of ZALTRAP and manufacturing ZALTRAP commercial supplies for Sanofi.

b. Bayer

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

	Three Months Ended June 30,	
Bayer Collaboration Revenue	2016	2015
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$167,492	$106,631
Cost-sharing of Regeneron EYLEA development expenses	2,224	2,464
Other	13,355	16,618
Total EYLEA	183,071	125,713
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept (REGN2176-3) development expenses	2,762	5,926
Other	2,607	2,598
Total PDGFR-beta	5,369	8,524
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	2,074	—
Other	1,382	—
Total Ang2	3,456	—
	$191,896	$134,237

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	Six Months Ended June 30,	
Bayer Collaboration Revenue	2016	2015
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$313,327	$196,057
Sales milestones	—	15,000
Cost-sharing of Regeneron EYLEA development expenses	4,967	5,121
Other	39,847	29,530
Total EYLEA	358,141	245,708
PDGFR-beta antibody:		
Cost-sharing of rinucumab/aflibercept (REGN2176-3) development expenses	4,658	7,180
Other	5,233	5,195
Total PDGFR-beta antibody	9,891	12,375
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	2,074	—
Other	1,382	—
Total Ang2 antibody	3,456	—
	$371,488	$258,083

EYLEA outside the United States

Under the terms of the license and collaboration agreement with Bayer for the global development and commercialization outside the United States of EYLEA, Bayer markets EYLEA outside the United States, where, for countries other than Japan, the companies share equally in profits and losses from sales of EYLEA. In Japan, the Company is entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales. In addition, all agreed-upon EYLEA development costs incurred by the Company and Bayer are shared equally. In the first quarter of 2015, the Company earned a $15.0 million sales milestone from Bayer upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period, which was the final milestone payment under the agreement.

PDGFR-beta antibody outside the United States

In 2014, the Company entered into an agreement with Bayer governing the joint development and commercialization outside the United States of an antibody product candidate to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), including in combination with aflibercept, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States.

Bayer 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 2013. In that regard, Bayer made a $5.0 million development milestone payment to the Company in the second quarter of 2015 (which was recognized as a substantive milestone).

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Ang2 antibody outside the United States

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

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

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

c. Mitsubishi Tanabe Pharma

In September 2015, the Company and Mitsubishi Tanabe Pharma Corporation ("MTPC") entered into a collaboration agreement providing MTPC with development and commercial rights to fasinumab, the Company's nerve growth factor antibody in late-stage clinical development, in certain Asian countries. In connection with the agreement, MTPC made a $10.0 million non-refundable up-front payment. In the first quarter of 2016, MTPC made additional payments of $45.0 million and $15.0 million to the Company, which were recorded as deferred revenue and will be recognized ratably as revenue over the same performance period as the up-front payment.

d. Intellia Therapeutics

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

Under the terms of the Product Collaboration agreement, the parties agreed to a target selection process, whereby the Company may obtain exclusive rights in up to 10 targets to be chosen by the Company during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Additionally, the Company may replace a

limited number of targets with substitute targets upon the payment of a replacement fee, in which case rights to the replaced target(s) will revert to Intellia.

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

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

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

e. Adicet Bio

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

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

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

4. Net Income Per Share

The Company's basic net income per share amounts have been computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Diluted net income per share includes the potential dilutive effect of other securities as if such securities were converted or exercised during the period, when the effect is dilutive. The calculations of basic and diluted net income per share are as follows:

	Three Months Ended June 30,	
	2016	2015
Net income - basic and diluted	$196,218	$194,643
(Shares in thousands)		
Weighted average shares - basic	104,633	102,886
Effect of dilutive securities:		
Stock options	10,141	9,438
Restricted stock	473	474
Warrants	984	2,461
Dilutive potential shares	11,598	12,373

Weighted average shares - diluted	116,231	115,259
Net income per share - basic	$1.88	$1.89
Net income per share - diluted	$1.69	$1.69

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	Six Months Ended June 30,	
	2016	2015
Net income - basic	$377,603	$270,664
Effect of dilutive securities:		
Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs	373	—
Net income - diluted	$377,976	$270,664
(Shares in thousands)		
Weighted average shares - basic	104,462	102,558
Effect of dilutive securities:		
Stock options	10,433	9,441
Restricted stock	471	471
Convertible senior notes	121	—
Warrants	1,130	2,492
Dilutive potential shares	12,155	12,404
Weighted average shares - diluted	116,617	114,962
Net income per share - basic	$3.61	$2.64
Net income per share - diluted	$3.24	$2.35

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

	Three Months Ended June 30,	
(Shares in thousands)	2016	2015
Stock options	7,904	3,366
Restricted stock	20	—
Convertible senior notes	96	1,539

	Six Months Ended June 30,	
(Shares in thousands)	2016	2015
Stock options	7,830	3,370
Restricted stock	19	—
Convertible senior notes	—	1,733

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5. Marketable Securities

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

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

As of June 30, 2016	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Unrestricted				
Corporate bonds	$801,408	$3,251	$(356)	$804,303
U.S. government and government agency obligations	62,864	269	(1)	63,132
Municipal bonds	12,693	41	(1)	12,733
Commercial paper	29,635	—	—	29,635
Certificates of deposit	8,014	—	—	8,014
Equity securities	17,005	9,891	(9,283)	17,613
	931,619	13,452	(9,641)	935,430
Restricted				
Equity Securities	50,000	3,078	—	53,078
	$981,619	$16,530	$(9,641)	$988,508

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

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

	June 30, 2016	December 31, 2015
Maturities within one year	$345,578	$236,121
Maturities after one year through five years	572,239	600,695
	$917,817	$836,816

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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 June 30, 2016	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$84,268	$ (157)	$104,096	$ (199)	$188,364	$ (356)
U.S. government and government agency obligations	2,000	(1)	—	—	2,000	(1)
Municipal bonds	2,982	(1)	—	—	2,982	(1)
Equity securities	5,717	(9,283)	—	—	5,717	(9,283)
	$94,967	$ (9,442)	$104,096	$ (199)	$199,063	$ (9,641)
As of December 31, 2015						
Corporate bonds	$668,199	$ (2,473)	$23,749	$ (92)	$691,948	$ (2,565)
U.S. government and government agency obligations	51,215	(193)	—	—	51,215	(193)
Municipal bonds	11,917	(11)	—	—	11,917	(11)
	$731,331	$ (2,677)	$23,749	$ (92)	$755,080	$ (2,769)

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

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

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6. Fair Value Measurements

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

As of June 30, 2016	Fair Value	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$804,303	—	$804,303
U.S. government and government agency obligations	63,132	—	63,132
Municipal bonds	12,733	—	12,733
Commercial paper	29,635	—	29,635
Certificates of deposit	8,014	—	8,014
Equity securities	17,613	$17,613	—
	935,430	17,613	917,817
Restricted			
Equity securities	53,078	—	53,078
	$988,508	$17,613	$970,895
As of December 31, 2015			
Available-for-sale marketable securities:			
Unrestricted			
Corporate bonds	$767,683	—	$767,683
U.S. government and government agency obligations	51,209	—	51,209
Municipal bonds	17,924	—	17,924
Equity securities	31,467	$31,467	—
	$868,283	$31,467	$836,816

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

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and six months ended June 30, 2016 and 2015. During the six months ended June 30, 2015, transfers of marketable securities from Level 2 to Level 1 were $91.4 million in connection with the lapse of the transfer restrictions on the Company's investment in Adverum Biotechnologies, Inc. (previously Avalanche Biotechnologies, Inc.) common shares in January 2015. The Company's policy for recognition of transfers between levels of the fair value hierarchy is to recognize any transfer at the beginning of the fiscal quarter in which the determination to transfer was made. There were no other transfers of marketable securities between Levels 1, 2, or 3 classifications during the six months ended June 30, 2016 and 2015. The Company's investment in Intellia common stock was classified as a Level 2 marketable security as of June 30, 2016 (see Note 5).

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As of June 30, 2016 and December 31, 2015, the Company had $0.2 million and $11.2 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") outstanding that will mature on October 1, 2016 unless earlier converted or repurchased (see Note 9). The fair value of the outstanding Notes was estimated to be $1.1 million and $72.8 million as of June 30, 2016 and December 31, 2015, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

7. Inventories

Inventories consist of the following:

	June 30, 2016	December 31, 2015
Raw materials	$73,971	$59,151
Work-in-process	165,869	132,068
Finished goods	14,421	11,197
Deferred costs	61,812	36,162
	$316,073	$238,578

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the three months ended June 30, 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $2.0 million and $6.4 million, respectively. For the six months ended June 30, 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $6.3 million and $8.1 million, respectively.

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	June 30, 2016	December 31, 2015
Accounts payable	$101,721	$140,962
Accrued payroll and related costs	114,603	133,223
Accrued clinical trial expense	88,639	88,297
Accrued sales-related charges, deductions, and royalties	177,377	195,986
Income taxes payable	170,269	—
Other accrued expenses and liabilities	107,034	85,644
	$759,643	$644,112

9. Debt

a. Convertible Debt

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

non-cash portion

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of the related Note conversions. The Company recorded the cost of the shares received, or $10.0 million, as Treasury Stock during the first half of 2016.

As of June 30, 2016, an aggregate principal amount of $0.2 million of Notes remained outstanding.

In the first half of 2015, the Company settled conversion obligations for $144.0 million principal amount of the Company's Notes. Upon settlement of the Notes, the Company paid $144.0 million in cash and issued 1,399,069 shares of Common Stock. In addition, in the first half of 2015, the Company allocated $694.7 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholder's equity, and recognized a $16.9 million loss on the debt extinguishment. In connection with the Note conversions in the first half of 2015, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 1,399,056 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 $117.5 million, as Treasury Stock during the first half of 2015.

Warrant Transactions

In November 2015, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $535.00 per share, during the period starting on November 16, 2015 and ending no later than February 9, 2016. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. As a result of the warrant holder closing out a portion of its hedge position in the first half of 2016, the Company paid a total of $135.2 million to reduce the number of warrants held by such warrant holder by 360,406 (which was the remaining maximum number of warrants to be reduced subject to the amendment agreement).

In February 2016, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 975,142. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $375.00 per share, during the period starting on February 22, 2016 and ending no later than May 5, 2016. The Company was able to settle, at its option, any payments due under the amendment agreement in cash or by delivering shares of Common Stock. As a result of the warrant holder closing out a portion of its hedge position during the first half of 2016, the Company paid a total of $106.9 million to reduce the number of warrants held by such warrant holder by 403,665.

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

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. The Company was obligated to settle any payments due under the amendment agreement in February 2015. Given that the amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the warrants subject to the agreement from additional paid-in capital to a liability in November 2014, with such liability

subsequently measured at fair value with changes in fair value recognized in earnings. In February 2015, the Company paid a total of $124.0 million to reduce the number of warrants held by such warrant holder by 416,480. Upon expiration of the November 2014 amended agreement, in the first quarter of 2015 the remaining warrants were re-measured at fair value, and $23.3 million was reclassified back to additional paid-in capital, consistent with the original classification of the warrants under the 2011 issuance. Total losses related to changes in fair value of the warrants during the first quarter of 2015 were not material.

b. Credit Facility

In March 2015, the Company entered into an agreement with a syndicate of lenders which provides for a $750.0 million senior unsecured five-year revolving credit facility. As of June 30, 2016, the Company had no borrowings outstanding under the credit facility and was in compliance with all credit facility covenants.

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10. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of $96.0 million and $133.4 million for the three months ended June 30, 2016 and 2015, respectively, and $244.8 million and $333.9 million for the six months ended June 30, 2016 and 2015, respectively. The Company's effective tax rate was 32.9% and 40.7% for the three months ended June 30, 2016 and 2015, respectively, and 39.3% and 55.2% for the six months ended June 30, 2016 and 2015, respectively. The Company's effective tax rate for the three and six months ended June 30, 2016 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation (see Note 13), the domestic manufacturing deduction, and the federal tax credit for increased research activities, offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee.

The Company's effective tax rate for the three and six months ended June 30, 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities.

The Company also recorded an income tax expense in its Statement of Comprehensive Income of $0.4 million and an income tax benefit of $1.6 million for the three and six months ended June 30, 2016, respectively, in connection with unrealized gains (losses) on available-for-sale marketable securities. The Company recorded an income tax benefit in its Statement of Comprehensive Income of $16.3 million and $18.9 million for the three and six months ended June 30, 2015, respectively, in connection with unrealized losses on available-for-sale marketable securities.

11. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable and accrued expenses as of June 30, 2016 and December 31, 2015 were $39.3 million and $50.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses as of June 30, 2015 and December 31, 2014 were $67.9 million and $56.2 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses as of December 31, 2014 was $7.5 million for the Company's conversion settlement obligation related to the Company's Notes which were surrendered for conversion but not settled as of December 31, 2014. There was no such liability as of June 30, 2016 and the amount of such liability was not material as of December 31, 2015 and June 30, 2015.

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

The Company recognized an additional facility lease obligation of $20.1 million during the six months ended June 30, 2015, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased. No such amount was recognized during the six months ended June 30, 2016.

12. Legal Matters

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

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

The Company is a party to patent infringement litigation initiated by the Company involving its European Patent No. 1,360,287 (the "'287 Patent"), its European Patent No. 2,264,163 (the "'163 Patent"), and its U.S. Patent No. 8,502,018 (the "'018 Patent"). Each of these patents concerns genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. Chimeric antibody sequences can be used to produce high-affinity fully human monoclonal antibodies. In these proceedings, the Company claims infringement of several claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable), and

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seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent, the '163 Patent, and the '018 Patent (as applicable). At this time, the Company is not able to predict the outcome of, or an estimate of gain or a range of possible loss, if any, related to, these proceedings.

Proceedings Relating to Praluent (alirocumab) Injection

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

A jury trial in this litigation was held from March 8 to March 16, 2016. During the course of the trial, the court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of Regeneron and Sanofi that there was no willful infringement of the asserted patent claims by Regeneron or Sanofi. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. On March 23 and March 24, 2016, the court held a permanent injunction hearing to determine whether Regeneron and Sanofi should be prohibited from commercializing Praluent. The parties to this litigation submitted post-trial briefs in the second quarter of 2016 and are awaiting the court's final opinion and judgment, including a decision on the permanent injunction. The Company and Sanofi plan to appeal any judgment or order that is adverse to the Company and Sanofi.

On July 25, 2016, Amgen filed a lawsuit against Regeneron, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of Amgen's European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, by Praluent. The lawsuit also seeks an injunction, damages, an accounting of profits, and costs and interest. Regeneron has not yet been served with the documents relating to the lawsuit.

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

from the distribution channels, and damages. Regeneron has not yet been served with the documents relating to the lawsuit.

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

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Proceedings Relating to Patents Owned by Genentech and City of Hope

On July 27, 2015, the Company and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Western Division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent (alirocumab), of U.S. Patent No. 7,923,221 (the "'221 Patent") jointly owned by Genentech, Inc. ("Genentech") and City of Hope relating to the production of recombinant antibodies by host cells. On the same day, the Company and Sanofi-Aventis U.S. LLC initiated an inter partes review in the United States Patent and Trademark Office ("USPTO") seeking a declaration of invalidity of certain claims of U.S. Patent No. 6,331,415 (the "'415 Patent") jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies by host cells. On February 5, 2016, the USPTO instituted an inter partes review of the validity of most of the patent claims of the '415 Patent for which review had been requested. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by the Company and Sanofi concerning the '221 Patent in the District Court and counterclaimed, alleging that the Company and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016 (subsequently vacated as noted below). On July 18, 2016, the court vacated the trial commencement date of September 27 in light of other pending motions.

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

Proceedings Relating to Shareholder Derivative Claims

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

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

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

13. Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-09 ("ASU 2016-09"), Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting, which the Company elected to early adopt during the second quarter of 2016. ASU 2016-09 requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital). This aspect of ASU 2016-09 was adopted prospectively, and accordingly, the Company recorded excess tax benefits of $39.8 million and $55.4 million, respectively, within income tax expense for the three and six months ended June 30, 2016, respectively. Included within income tax expense for the six months ended June 30, 2016 is $15.6 million of excess tax benefits, which was previously recorded to additional paid-in capital during the first quarter of 2016. The amendments also require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Furthermore, the amendments require that excess tax benefits be classified as an

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

operating activity in the statement of cash flows (such amounts were previously included as a financing activity in the statement of cash flows); the Company also adopted this provision of ASU 2016-09 prospectively.

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

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

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

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

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron," "Company," "we," "us," and "our"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of our products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, and REGN2222; the likelihood and timing of achieving any of our anticipated clinical development milestones; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation EYLEA, Praluent, sarilumab, dupilumab, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. We commercialize medicines for eye diseases, high low-density lipoprotein (LDL) cholesterol, and a rare inflammatory condition and have product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis (RA), asthma, atopic dermatitis, pain, cancer, and infectious diseases.

Our total revenues were $1,212.6 million in the second quarter and $2,413.5 million in the first half of 2016, compared to $998.6 million in the second quarter and $1,868.2 million in the first half of 2015. Our net income was $196.2 million, or $1.69 per diluted share, in the second quarter and $377.6 million, or $3.24 per diluted share, in the first half of 2016, compared to net income of $194.6 million, or $1.69 per diluted share, in the second quarter and $270.7 million, or $2.35 per diluted share, in the first half of 2015. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

- EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, is available in the United States, European Union (EU), Japan, and other countries outside the United States for the treatment of neovascular

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

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

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

We have 15 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 14 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune® technology.

Trap-based Clinical Programs	
EYLEA	In Phase 3 clinical development for the treatment of Neovascular Glaucoma (NVG) (in Japan) in collaboration with Bayer. Phase 3 study for the treatment of non-proliferative diabetic retinopathy (NPDR) in patients without DME initiated in the first quarter of 2016. As described below, aflibercept is also being studied in combination with (i) rinucumab, an antibody to Platelet Derived Growth Factor Receptor Beta (PDGFR-beta), and (ii) nesvacumab, an antibody to angiopoietin-2 (Ang2).
Antibody-based Clinical Programs in	

Collaboration with Sanofi Praluent	Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events.
Sarilumab (REGN88)	Antibody to the interleukin-6 receptor (IL-6R). In clinical development in rheumatoid arthritis (Phase 3) and non-infectious uveitis (Phase 2).
Dupilumab (REGN668)	Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in adults (Phase 3), atopic dermatitis in pediatric patients (Phase 2), asthma (Phase 3), and eosinophilic esophagitis (EoE) (Phase 2). Plan to conduct Phase 3 studies in patients with nasal polyps.
REGN2810	Antibody to programmed cell death protein 1 (PD-1). In Phase 1 clinical development in solid tumors and advanced hematologic malignancies. Potentially pivotal Phase 2 study for the treatment of advanced cutaneous squamous cell carcinoma initiated in the second quarter of 2016. REGN 2810 is also being studied in

combination with REGN1979 in B-cell malignancies.	
Antibody-based Clinical Program in Collaboration with Bayer	
Rinucumab/aflibercept (REGN2176-3)**	Combination product comprised of an antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection for use in ophthalmology. In Phase 2 clinical development for the treatment of wet AMD. Fast Track designation received from the U.S. Food and Drug Administration (FDA) for the treatment of patients with wet AMD.
Nesvacumab/aflibercept (REGN910-3)**	Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 2 studies for the treatment of wet AMD and DME initiated in the first quarter of 2016.
Antibody-based Clinical Program in Collaboration with Mitsubishi Tanabe Pharma	
Fasinumab (REGN475)*	Antibody to Nerve Growth Factor (NGF). In Phase 2/3 clinical development (16-week

study) for pain due to osteoarthritis and chronic low back pain.	
Phase 3 long-term safety and efficacy study in patients with osteoarthritis of knee and hip initiated in the first quarter of 2016.	
Phase 2b/3 study for chronic low back pain initiated in the first quarter of 2016.	

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Antibody-based Clinical Programs Developing Independently	
REGN2222*	Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. In Phase 3 clinical development for prevention of RSV infection.
Evinacumab (REGN1500)*	Antibody to Angptl-3. In Phase 1/2 clinical development for the treatment of homozygous familial hypercholesterolemia (HoFH) and severe forms of hyperlipidemia.
Trevogrumab (REGN1033)*	Antibody to myostatin (GDF8). Phase 2 monotherapy clinical development in skeletal muscle disorders completed. Combination therapy plans are in development.
REGN1908-1909*	Antibody to Feld1. In Phase 1 clinical development against allergic disease.
REGN1979	Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, and Acute

Lymphoblastic Leukemia. REGN1979 is also being studied in combination with REGN2810 in B-cell malignancies.

REGN3470-3471-3479 Antibody to Ebola virus. Phase 1 study in healthy volunteers initiated in the second quarter of 2016. Also in the second quarter of 2016, the FDA granted orphan-drug designation for the treatment of Ebola virus infection.

REGN2477 Antibody to Activin A being developed for Fibrodysplasia Ossificans Progressiva (FOP). Phase 1 study in healthy volunteers initiated in the second quarter of 2016.

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

** Antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other

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

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

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

Marketed Products

EYLEA (aflibercept) Injection

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

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

Net product sales of EYLEA in the United States were $830.9 million in the second quarter and $1,611.8 million in the first half of 2016, compared to $654.6 million in the second quarter and $1,195.7 million in the first half of 2015. Bayer records revenue from sales of EYLEA outside the United States, which were $486.2 million in the second quarter and $905.1 million in the first half of 2016, compared to $337.8 million in the second quarter and $629.6 million in the first half of 2015.

Praluent (alirocumab) Injection

In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated dose of a statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent. In July 2016, the Japanese Ministry of Health, Labour and Welfare (MHLW) granted marketing and manufacturing authorization for Praluent for the treatment of uncontrolled LDL cholesterol, in certain adult patients with hypercholesterolemia at high cardiovascular risk.

Under our collaboration agreement, Sanofi records product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States and thus far have not exercised our option to co-promote Praluent outside the United States. We and Sanofi share profits and losses from sales of Praluent. Net product sales of Praluent were $24.5 million in the second quarter and $37.4 million in the first half of 2016.

ARCALYST (rilonacept) Injection for Subcutaneous Use

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

Net product sales of ARCALYST were $3.3 million in the second quarter and $6.6 million in the first half of 2016, compared to $3.2 million in the second quarter and $6.7 million in the first half of 2015.

Trap-based Clinical Programs

EYLEA - Ophthalmologic Diseases

Overview

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

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

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Neovascular Glaucoma

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

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

Diabetic Retinopathy

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

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

Late-Stage Antibody-based Clinical Programs

Praluent for LDL cholesterol reduction

Overview

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

Clinical Programs

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

trial received Praluent 300 milligrams (mg) (most in combination with statins) every four weeks and patients in the CHOICE II trial received Praluent 150 mg monotherapy and in combination with non-statin lipid lowering therapy every four weeks.

In the first quarter of 2016, we and Sanofi announced positive results from the Phase 3 ODYSSEY ESCAPE trial evaluating Praluent in patients with HeFH, whose cholesterol levels required chronic, weekly or bi-weekly apheresis therapy. The trial met its primary endpoint, demonstrating that patients who added Praluent to their existing treatment regimen significantly reduced the frequency of their apheresis therapy by 75%, compared to placebo ($p<0.0001$). Sixty-three percent of patients treated with Praluent

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no longer required apheresis, compared to zero percent of placebo patients. Apheresis is a procedure where bad (LDL) cholesterol is removed from the blood, in a process similar to kidney dialysis. The most common adverse events (AEs) in the trial were fatigue (15% Praluent; 10% placebo), nasopharyngitis (10% Praluent; 10% placebo), diarrhea (10% Praluent; 0% placebo), myalgia (10% Praluent; 5% placebo), upper respiratory infection (7% Praluent; 19% placebo), headache (7% Praluent; 5% placebo), arthralgia (7% Praluent; 10% placebo), and back pain (5% Praluent; 10% placebo). Detailed data will be presented at future medical conferences.

In the first quarter of 2016, the Data Monitoring Committee (DMC) of the ODYSSEY OUTCOMES study completed the first interim analysis. In accordance with the protocol, the DMC performed a futility assessment. The DMC recommended the study continue with no changes. Regeneron remains blinded to the actual results of this analysis.

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

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

Overview

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

Rheumatoid Arthritis

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

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

SARIL-RA-EASY was designed to evaluate the technical performance and usability of the sarilumab autoinjector device. There were no product technical failures with the autoinjector, the primary endpoint of the study.

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

A BLA for U.S. regulatory approval of sarilumab was accepted for review by the FDA in December 2015. The target date for an FDA decision on the BLA is October 30, 2016. In addition, in July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorization Application (MAA) for sarilumab.

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Non-infectious Uveitis

Phase 2 SARIL-NIU-SATURN Study. SARIL-NIU-SATURN was a small Phase 2, randomized double-masked, placebo-controlled study (n=58) conducted to assess the effect of sarilumab on non-infectious uveitis of the posterior ocular segment. We reported results of this study at the pre-specified primary endpoint (week 16) during 2015. The full 52-week data are expected in the second half of 2016.

Dupilumab (REGN668; IL-4R Antibody) for allergic and inflammatory conditions

Overview

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

Atopic Dermatitis

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

In 2014, the FDA granted Breakthrough Therapy designation to dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. This designation is based on positive results from Phase 1 and 2 clinical trials, the determination that atopic dermatitis is a serious disease, and preliminary clinical evidence that indicates that the drug may demonstrate substantial improvement over existing therapies. A BLA for dupilumab in the United States was recently submitted to the FDA.

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

In April 2016, we and Sanofi announced positive top-line data from the Phase 3 LIBERTY AD SOLO 1 and SOLO 2 studies. These studies met their primary endpoints, and treatment with dupilumab as monotherapy significantly improved measures of overall disease severity, skin clearing, itching, quality of life, and mental health. A total of 1,379 adult patients with moderate-to-severe atopic dermatitis were enrolled in the identically-designed SOLO 1 and SOLO 2 trials. Patients were enrolled if they were not adequately controlled with topical medications, or if topical treatment was not medically advisable. All patients were assessed via the 5-point Investigator's Global Assessment (IGA) scale, ranging from 0 (clear) to 4 (severe); entry criteria required a baseline score of 3 or 4. Patients were also assessed using the Eczema Area and Severity Index (EASI) and other measures. Patients were randomized into one of three treatment groups: dupilumab 300 mg subcutaneously once per week, dupilumab 300 mg subcutaneously every two weeks, or placebo for 16 weeks following an initial dupilumab loading dose of 600 mg subcutaneously, or placebo. Results at 16 weeks included the following:

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

weeks, compared to 38% and 31% for placebo (p<0.0001).

For SOLO 1 and SOLO 2, respectively, 52.5% and 48% of patients who received dupilumab 300 mg weekly, and 51% and 44% of patients who received dupilumab 300 mg every two weeks, achieved EASI-75 compared to 15% and 12% with placebo (p<0.0001). This was the key secondary endpoint in the United States and one of the primary endpoints in the EU.

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

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

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

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

The secondary endpoint 52-week results were the following:

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

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

The overall rate of AEs in the LIBERTY AD CHRONOS study was comparable between the dupilumab with TCS groups (83% for the weekly dose (qw) and 88% for the every two weeks (q2w) dosing group) and the placebo with TCS group (84%). The rate of serious AEs was comparable between the dupilumab with TCS groups (3% (qw) and 4% (q2w)) and placebo with TCS group (5%). Serious and/or severe infections were numerically higher in the placebo with TCS group (1% in both dupilumab groups and 2% placebo). Adverse events that were noted to have a higher rate with dupilumab included injection site reactions (20% (qw) and 16% (q2w) dupilumab; 9% placebo) and conjunctivitis (19% (qw) and 13% (q2w) dupilumab; 8% placebo); 22% of patients on placebo, and 23% (qw) and 28% (q2w) of patients on dupilumab reported a history of allergic conjunctivitis at study entry.

Phase 2 Study in Pediatric Patients. In 2015, a Phase 2 pharmacokinetic and safety study in pediatric patients (6-17 years of age) with moderate-to-severe atopic dermatitis was initiated, and data are expected in the second half of 2016.

Asthma

Phase 3 Study. A Phase 3 trial, LIBERTY ASTHMA QUEST, in patients with uncontrolled persistent asthma was initiated in the second quarter of 2015. LIBERTY ASTHMA QUEST is expected to serve as the second required pivotal efficacy study, since, based on discussions with the FDA, the Phase 2b study will also be considered a pivotal efficacy study. The global, placebo-controlled Phase 3 study is expected to enroll more than 1,600 patients with

uncontrolled persistent asthma and will evaluate two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

Nasal Polyps

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

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Eosinophilic Esophagitis

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

REGN2222 (RSV-F Antibody) for RSV

Overview

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

Clinical Program

Based on clinical results from a Phase 1 study, a Phase 3 pivotal clinical study of REGN2222 (NURSERY Pre-Term) was initiated in 2015 and is currently enrolling patients.

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

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

Overview

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

Clinical Program

In the second quarter of 2015, a Phase 2/3 clinical study (16-weeks) in patients with moderate-to-severe osteoarthritis pain of the hip or knee who have a history of inadequate pain relief or intolerance to current analgesic therapies was initiated. In May 2016, we announced positive top-line data from the study. At 16 weeks, patients treated with all four doses of fasinumab demonstrated a statistically significant improvement in pain relief, the primary endpoint of the study, as well as improvements in the secondary measure evaluating physical function. The U.S. study enrolled 421 adult patients with moderate-to-severe osteoarthritis of the hip or knee who had a history of inadequate pain relief or intolerance to acetaminophen, and at least one oral nonsteroidal anti-inflammatory drug (NSAID) and an opioid. Patients in the study were experiencing significant pain at baseline with an average pain score of 6.3 on a 10-point scale. Patients were evaluated for pain, stiffness, and physical function using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in addition to other measures. Patients were randomized to one of five treatment groups in a 1:1:1:1:1 fashion; fasinumab 1mg, 3mg, 6mg, 9mg, or placebo, all delivered subcutaneously every 4 weeks through week 12, with the primary efficacy measured at week 16. Following week 16, patients are being studied for an additional 20 weeks off treatment. On the primary endpoint, fasinumab-treated patients reported less pain at 16 weeks when compared to placebo on the 10-point WOMAC subscale for pain (-3.03 to -3.65 fasinumab vs. -2.25 placebo; p=0.03 through p=0.0001). The safety analysis includes all results at the time of the primary efficacy analysis; complete data will be reported when all patients complete the full 36 weeks. Overall incidence of AEs, including serious and severe events, was similar across the fasinumab groups and placebo. As expected with antibodies to NGF, there was an increase in certain neuro-musculoskeletal AEs in the fasinumab treatment groups (17% combined fasinumab; 6% placebo) including arthralgia, paraesthesia, hypoaesthesia, and peripheral edema. We plan to present detailed results of the study at an upcoming medical congress.

In the first quarter of 2016, the FDA confirmed that we may proceed with studies of longer than sixteen-week duration. A Phase 3 long-term safety and efficacy study in patients with pain due to osteoarthritis of the knee or hip was initiated in the first quarter of 2016. A Phase 2b/3 study in chronic low back pain was also initiated in the first quarter of 2016.

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

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Research Programs

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

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

Collaboration Agreements

Collaborations with Sanofi

Antibodies. Since November 2007, we and Sanofi have been parties to a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement (Antibody Discovery Agreement) and a License and Collaboration Agreement (each as amended), collectively referred to as the Antibody Collaboration. Pursuant to the Antibody Discovery Agreement, as amended, Sanofi is responsible for funding up to $130.0 million of our antibody discovery activities in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. For each drug candidate identified through discovery research under the Antibody Discovery Agreement, Sanofi has the option to license rights to the candidate under the License and Collaboration Agreement. If it elects to do so, Sanofi will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with Sanofi generally funding these costs as they are incurred by us, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose.

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

Immuno-Oncology. In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable up-front payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million (IO Discovery Budget) to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Sanofi will reimburse us for up to $825.0 million (IO Discovery Funding) of these costs, subject to certain annual limits. We will reimburse Sanofi for half of the development costs they funded that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from our share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. With regard to product candidates for which proof-of-concept is established, Sanofi will have the option to license rights to the product candidate pursuant to the IO License and Collaboration Agreement.

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

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Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop our antibody product candidate targeting PD-1 (REGN2810). We have principal control over the development of REGN2810, and the parties share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. We will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

Collaborations with Bayer

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

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

PDGFR-beta antibody outside the United States. In January 2014, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of rinucumab, an antibody product candidate to PDGFR-beta, including in combination with aflibercept, for the treatment of ocular diseases or disorders. Rinucumab/aflibercept, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with aflibercept, is being developed under the agreement. Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer will have a right to opt-in to license and collaborate on further development and commercialization outside the United States. In connection with the agreement, Bayer is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. We are eligible to receive a $10.0 million additional development milestone payment from Bayer, although this payment could be reduced by half if Bayer does not opt-in to the collaboration.

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

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

us, and is responsible for certain royalties payable to Sanofi on sales of the product outside of the United States. Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing an Ang2 antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both us and Bayer.

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Collaboration with Mitsubishi Tanabe Pharma

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

Collaboration with Intellia Therapeutics

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

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

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

Certain targets that either we or Intellia select pursuant to the target selection process may be subject to a co-development and co-commercialization arrangement at our option or Intellia’s option, as applicable. The terms of the co-development and co-commercialization agreement are expected to be finalized by the end of 2016. Transthyretin amyloidosis (ATTR), the first target selected by us, will be subject to the co-development and co-commercialization arrangement between the parties.

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

Collaboration with Adicet Bio

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

five-year research term.

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

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

General

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

Our ability to continue to generate profits and to generate positive cash flow from operations over the next several years depends significantly on our continued success in commercializing EYLEA. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of Praluent and preparation for potential commercialization of our late-stage antibody product candidates, approximately half of which we expect to be reimbursed by Sanofi under the companies' collaboration agreement. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our marketed products, the scope and progress of our research and development efforts, the timing of certain expenses, the continuation of our collaborations, in particular with Sanofi and Bayer, including our share of collaboration profits or losses from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators, and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

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

Trap-based Clinical Program:

	2016 Events to Date	2016-2017 Plans (next 12 months)
EYLEA	Bayer received regulatory approval for EYLEA for various indications and continued to pursue regulatory applications for marketing approval in additional countries Initiated Phase 3 study for the treatment of NPDR in patients without DME Reported positive top-line results from Phase 3 study in Japan for the treatment of NVG	Bayer to submit for additional regulatory approvals outside the United States for various indications Regulatory agency decisions on applications outside the United States for various indications

Antibody-based Clinical Programs:

	2016 Events to Date	2016-2017 Plans (next 12 months)
Praluent (PCSK9 Antibody)	Reported positive results from Phase 3 ODYSSEY ESCAPE trial	Report additional data from Phase 3 ODYSSEY program
	The DMC of the ODYSSEY OUTCOMES study completed the first interim analysis for futility and	Submit for additional regulatory approvals outside the United States

recommended the study continue with no changes	Regulatory agency and reimbursement authority decisions on applications outside the United States
Supplemental BLA for monthly dosing regimen accepted for review by the FDA	Prespecified early-stopping interim analysis by DMC of ODYSSEY OUTCOMES trial
Regulatory application submitted for monthly dosing regimen in the EU	

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

Trevogrumab (GDF8 Antibody)	Initiate Phase 1 combination therapy studies with REGN2477

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Antibody-based Clinical Programs (continued):

	2016 Events to Date	2016-2017 Plans (next 12 months)
REGN2810 (PD-1 Antibody)	Continued patient enrollment in Phase 1 study	Continue patient enrollment in Phase 1 and Phase 2 studies
	Initiated Phase 2 potentially pivotal study for the treatment of advanced cutaneous squamous cell carcinoma	Initiate later-stage pivotal studies
	Initiated Phase 1 study in combination with REGN1979 for treatment of B-cell malignancies	
	Presented positive Phase 1 results from a dose-ranging study in heavily-pretreated patients with solid tumor cancers	
REGN1908-1909 (Feld1 Antibody)	Completed initial proof-of-concept study	Continue early stage development
REGN1979 (CD20 and CD3 Antibody)	Continued patient enrollment in Phase 1 study	Complete patient enrollment in Phase 1 study
	Initiated Phase 1 study in combination with REGN2810 for treatment of B-cell malignancies	
REGN3470-3471-3479 (Antibody to Ebola virus)	Initiated Phase 1 study in healthy volunteers	Continue enrollment in Phase 1 study
	FDA granted orphan-drug designation for the treatment of Ebola virus infection	
REGN2477 (Activin A Antibody)	Initiated Phase 1 study in healthy volunteers	Continue patient enrollment in Phase 1 study

Corporate Information

We were incorporated in the State of New York in 1988 and publicly listed in 1991. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number at that address is (914) 847-7000.

We make available free of charge on or through our Internet website (http://www.regeneron.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Investors and other interested parties should note that we use our media and investor relations website (http://newsroom.regeneron.com) and our social media channels to publish important information about Regeneron, including information that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our media and investor relations website and the social media channels listed on our media and investor relations website, in addition to our SEC filings, press releases, conference calls, and webcasts.

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Results of Operations

Three Months Ended June 30, 2016 and 2015

Net Income

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

(In millions)	2016	2015
Revenues	$1,212.6	$998.6
Operating expenses	(921.0)	(653.8)
Other income (expense)	0.6	(16.8)
Income before income taxes	292.2	328.0
Income tax expense	(96.0)	(133.4)
Net income	$196.2	$194.6

Revenues

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

(In millions)	2016	2015
Net product sales	$834.2	$657.8
Collaboration revenue:		
Sanofi	163.4	195.1
Bayer	191.9	134.2
Total collaboration revenue	355.3	329.3
Other revenue	23.1	11.5
Total revenues	$1,212.6	$998.6

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in 2014, macular edema following BRVO in 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended June 30, 2016, EYLEA net product sales increased to $830.9 million from $654.6 million for the three months ended June 30, 2015 due to higher sales volume. For the three months ended June 30, 2016 and 2015, we also recognized ARCALYST net product sales of $3.3 million and $3.2 million, respectively.

For the three months ended June 30, 2016 and 2015, we recorded 56% and 69%, respectively, of our 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, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

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(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of March 31, 2016	$ 7.8	$ 33.7	$ 0.9	$42.4
Provision related to current period sales	22.4	38.5	9.4	70.3
Credits/payments	(18.6)	(44.1)	(9.2)	(71.9)
Balance as of June 30, 2016	$ 11.6	$ 28.1	$ 1.1	$40.8
Balance as of March 31, 2015	$ 4.7	$ 32.9	$ 0.5	$38.1
Provision related to current period sales	14.1	30.0	2.1	46.2
Credits/payments	(13.3)	(23.4)	(2.1)	(38.8)
Balance as of June 30, 2015	$ 5.5	$ 39.5	$ 0.5	$45.5

Sanofi Collaboration Revenue

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

Sanofi Collaboration Revenue	Three Months Ended June 30,	
(In millions)	2016	2015
Antibody:		
Reimbursement of Regeneron research and development expenses	$144.2	$211.5
Reimbursement of Regeneron commercialization-related expenses	85.9	27.3
Regeneron's share of losses in connection with commercialization of antibodies	(122.1)	(46.3)
Other	3.0	2.6
Total Antibody	111.0	195.1
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	32.4	—
Other	20.0	—
Total Immuno-oncology	52.4	—
Total Sanofi collaboration revenue	$163.4	$195.1

In the second quarter of 2016, Sanofi's reimbursement of our antibody research and development expenses consisted of $48.3 million under our Antibody Discovery Agreement and $95.9 million under our License and Collaboration Agreement, compared to $56.4 million and $155.1 million, respectively, in the second quarter of 2015. The lower reimbursement of research and development costs in the second quarter of 2016, compared to the same period in 2015, was primarily due to decreased collaboration development activities for dupilumab, Praluent, sarilumab, and REGN2222. In 2016, Sanofi no longer co-develops and reimburses us for development activities for REGN2222.

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

During the three months ended June 30, 2015, we and Sanofi shared pre-launch commercial expenses related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In addition, effective in the first quarter of 2016, we and Sanofi also began sharing pre-launch commercialization expenses related to dupilumab for atopic dermatitis. As such, we recorded our share of losses in connection with preparing to commercialize Praluent, sarilumab, and dupilumab within Sanofi collaboration revenue. In July 2015, the FDA approved Praluent in the United States and in September 2015, the European

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Commission granted marketing authorization of Praluent. Therefore, commencing in the third quarter of 2015, we also recorded within Sanofi collaboration revenue our share of the Antibody Collaboration's losses in connection with commercialization of Praluent. Sanofi provides us with an estimate of our share of the losses from preparing to commercialize, or commercialization (as applicable), of antibodies for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. We and Sanofi incurred higher commercialization expenses for Praluent in the second quarter of 2016, compared to the same period in 2015, primarily in connection with launching the product in the United States and certain European countries. Praluent net product sales, which are recorded by Sanofi, were $24.5 million in the second quarter of 2016.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of June 30, 2016, $61.4 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology. In the second quarter of 2016, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $22.6 million under our IO Discovery Agreement, and $9.8 million under our IO License and Collaboration Agreement related to REGN2810.

Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements. As of June 30, 2016, $560.0 million of the up-front payments was deferred and will be recognized ratably as revenue in future periods.

Bayer Collaboration Revenue

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

Bayer Collaboration Revenue	Three Months Ended June 30,	
(In millions)	2016	2015
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$167.5	$106.6
Cost-sharing of Regeneron EYLEA development expenses	2.2	2.5
Other	13.4	16.6
Total EYLEA	183.1	125.7
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	2.8	5.9
Other	2.6	2.6
Total PDGFR-beta antibody	5.4	8.5
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	2.1	—
Other	1.3	—
Total Ang2 antibody	3.4	—
Total Bayer collaboration revenue	$191.9	$134.2

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

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Regeneron's Net Profit from EYLEA Sales Outside the United States	Three Months Ended June 30,	
(In millions)	2016	2015
Net product sales outside the United States	$486.2	$337.8
Regeneron's share of collaboration profit from sales outside the United States	181.0	120.4
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(13.5)	(13.8)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$167.5	$106.6

Bayer records revenue from sales of EYLEA outside the United States. Bayer provides us with an estimate of our share of the profit or loss, including the percentage of sales in Japan that we earned, from commercialization of EYLEA outside the United States for the most recent fiscal quarter; these estimates are reconciled to actual results in the subsequent fiscal quarter, and our portion of the profit or loss is adjusted accordingly, as necessary. In the second quarter of 2016 and 2015, our share of the profit we earned from commercialization of EYLEA outside the United States was partly offset by our contractual obligation to reimburse Bayer for a portion of the agreed-upon development expenses previously incurred by Bayer.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, including Bayer's share of royalties payable to Genentech pursuant to a license and settlement agreement (see "Cost of Collaboration and Contract Manufacturing" below for further details) in connection with sales of EYLEA outside the United States and reimbursements for producing EYLEA commercial supplies for Bayer. In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer. As of June 30, 2016, $9.7 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Bayer is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer made a $5.0 million development milestone payment to us in the second quarter of 2015, which was recognized as revenue in that quarter and included in "Cost-sharing of REGN2176-3 development expenses" in the table above.

Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front and non-substantive milestone payments received in 2014. As of June 30, 2016, $4.3 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

As described above under "Collaboration Agreements - Collaborations with Bayer - Ang2 antibody outside the United States," in March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. Nesvacumab/aflibercept, a combination product candidate comprised of an antibody to Ang2 co-formulated with aflibercept, is being developed under the agreement. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to us and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. As of June 30, 2016, $49.8 million of the up-front and other payments was deferred and will be recognized ratably as revenue in future periods.

Other Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the second quarter of both 2016 and 2015, we recognized $5.9 million of revenue related to this agreement. As of June 30, 2016, $45.6 million of the August 2010 technology licensing payment received from Astellas was deferred and will continue to be recognized as revenue in future periods.

In February 2015, we and Sanofi entered into an amended and restated ZALTRAP agreement (Amended ZALTRAP Agreement). Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all

development and commercialization activities and reimburses Regeneron for its costs for any such activities. Sanofi also pays us a percentage of aggregate net sales of ZALTRAP. In connection with the Amended ZALTRAP Agreement, we recorded $9.3 million of revenue in the second quarter of 2016 primarily related to (i) a percentage of net sales of ZALTRAP for the quarter that Sanofi is obligated to pay us and (ii) manufacturing

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ZALTRAP commercial supplies for Sanofi. In the second quarter of 2015, in connection with the Amended ZALTRAP Agreement, we recorded $3.2 million of revenue primarily related to a percentage of net sales of ZALTRAP.

Expenses

Total operating expenses increased to $921.0 million in the second quarter of 2016 from $653.8 million in the second quarter of 2015. Our average headcount in the second quarter of 2016 increased to 4,758 from 3,574 in the same period in 2015, principally in connection with expanding our research and development, manufacturing, and commercialization activities.

Operating expenses in the second quarter of 2016 and 2015 included a total of $131.7 million and 94.3 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 second quarter of 2016 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2015 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $559.9 million in the second quarter of 2016 from $390.3 million in the same period of 2015. The following table summarizes the major categories of our research and development expenses:

Research and Development Expenses	Three Months Ended June 30,		Increase
(In millions)	2016	2015	(Decrease)
Payroll and benefits [1]	$151.9	$120.6	$ 31.3
Clinical trial expenses	82.0	74.8	7.2
Clinical manufacturing costs [2]	139.2	96.1	43.1
Research and other development costs	112.4	39.3	73.1
Occupancy and other operating costs	43.8	34.9	8.9
Cost-sharing of Bayer and Sanofi development expenses [3]	30.6	24.6	6.0
Total research and development expenses	$559.9	$390.3	$ 169.6

[1] Includes Non-cash Compensation Expense of $66.6 million for the three months ended June 30, 2016 and $51.2 million for the three months ended June 30, 2015.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer, New York manufacturing facility. Also includes Non-cash Compensation Expense of $12.7 million for the three months ended June 30, 2016 and $8.8 million for the three months ended June 30, 2015.

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

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased primarily due to (i) the initiation of additional clinical studies of fasinumab and (ii) additional enrollment in REGN2810 clinical studies as well as the initiation of a clinical study in REGN2810 for the treatment of advanced cutaneous squamous cell carcinoma, partly offset by lower costs in connection with our dupilumab clinical program as some later-stage studies wind down. Clinical manufacturing costs increased primarily due to costs related to purchases of higher volumes of clinical manufacturing supplies and manufacturing additional drug supplies of fasinumab and REGN2810. Research and other development costs

increased primarily due to the $75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia. Cost-sharing of Bayer HealthCare and Sanofi development expenses increased primarily due to our obligation to fund 20% of Sanofi's Phase 3 dupilumab development costs, which commenced during the first quarter of 2016.

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

Project Costs	Three Months Ended June 30,		Increase
(In millions)	2016	2015	(Decrease)
Praluent	$46.3	$49.6	$ (3.3)
Dupilumab	111.4	113.0	(1.6)
Sarilumab	12.8	20.1	(7.3)
Fasinumab	46.7	5.5	41.2
REGN2222	17.7	10.9	6.8
REGN2810	22.5	7.5	15.0
Other antibody candidates in clinical development	58.5	56.2	2.3
Other research programs and unallocated costs [(1)]	244.0	127.5	116.5
Total research and development expenses	$559.9	$390.3	$ 169.6

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

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

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

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

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Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $292.0 million in the second quarter of 2016 from $174.6 million in the second quarter of 2015 primarily due to (i) higher commercialization-related expenses associated with EYLEA and Praluent, (ii) higher contributions to not-for-profit organizations, including donations to independent not-for-profit patient assistance organizations, (iii) higher headcount and headcount-related costs, and (iv) higher Non-cash Compensation Expense principally for the reason described under "Expenses" above. Selling, general, and administrative expenses included $47.7 million and $32.2 million of Non-cash Compensation Expense in the second quarter of 2016 and 2015, respectively.

Cost of Goods Sold

Cost of goods sold was $41.2 million in the second quarter of 2016 and $60.9 million in the second quarter of 2015. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold decreased principally due to a decrease in royalties since our obligation to pay Genentech based on sales of EYLEA ended in May 2016. In addition, in the second quarter of 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $2.0 million and $6.4 million, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer, decreased to $27.8 million in the second quarter of 2016 from $28.0 million in the second quarter of 2015. This decrease was primarily due to (i) the fact that, effective May 2016, we are no longer obligated to pay royalties to Genentech based on sales of EYLEA (as described above), partly offset by (ii) recognition of costs associated with commercial supplies of ZALTRAP manufactured for Sanofi in the second quarter of 2016.

Other Income and Expense

Interest and other expense in the second quarter of 2016 decreased compared to the second quarter of 2015 primarily due to (i) a decrease in interest expense related to conversions of a substantial portion of our 1.875% convertible senior notes (the Notes) in 2015, and (ii) recognition of a $0.5 million and $16.0 million loss in the second quarter of 2016 and 2015, respectively, in connection with Notes which were surrendered for conversion during those quarters.

Income Taxes

In the second quarter of 2016 and 2015, we recorded income tax expense of $96.0 million and $133.4 million, respectively. The effective tax rate was 32.9% and 40.7% for the second quarter of 2016 and 2015, respectively. The second quarter 2016 effective tax rate was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, and the federal tax credit for increased research activities, partly offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. As described in Note 13 of our Condensed Consolidated Financial Statements, we prospectively adopted Accounting Standards Update 2016-09 (ASU 2016-09), Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting, during the second quarter of 2016. ASU 2016-09 requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital).

The effective tax rate for the second quarter of 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-tax deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities.

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Results of Operations
Six Months Ended June 30, 2016 and 2015
Net Income
Net income for the six months ended June 30, 2016 and 2015 consists of the following:

(In millions)	2016	2015
Revenues	$2,413.5	$1,868.2
Operating expenses	(1,792.5)	(1,239.8)
Other income (expense)	1.4	(23.9)
Income before income taxes	622.4	604.5
Income tax expense	(244.8)	(333.8)
Net income	$377.6	$270.7

Revenues
Revenues for the six months ended June 30, 2016 and 2015 consist of the following:

(In millions)	2016	2015
Net product sales	$1,618.4	$1,202.4
Collaboration revenue:		
Sanofi	383.1	368.4
Bayer	371.5	258.1
Total collaboration revenue	754.6	626.5
Other revenue	40.5	39.3
Total revenues	$2,413.5	$1,868.2

Net Product Sales
Net product sales consist of U.S. sales of EYLEA and ARCALYST. For the six months ended June 30, 2016, EYLEA net product sales increased to $1,611.8 million from $1,195.7 million for the six months ended June 30, 2015 due to higher sales volume. For the six months ended June 30, 2016 and 2015, we also recognized ARCALYST net product sales of $6.6 million and $6.7 million, respectively.
For the six months ended June 30, 2016 and 2015, we recorded 58% and 69%, respectively, of our 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, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

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(In millions)	Rebates & Chargebacks	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2015	$ 6.4	$ 48.3	$ 0.5	$55.2
Provision related to current period sales	41.3	74.3	12.3	127.9
Credits/payments	(36.1)	(94.5)	(11.7)	(142.3)
Balance as of June 30, 2016	$ 11.6	$ 28.1	$ 1.1	$40.8
Balance as of December 31, 2014	$ 3.1	$ 21.2	$ 0.5	$24.8
Provision related to current period sales	25.5	54.7	3.5	83.7
Credits/payments	(23.1)	(36.4)	(3.5)	(63.0)
Balance as of June 30, 2015	$ 5.5	$ 39.5	$ 0.5	$45.5

Sanofi Collaboration Revenue

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

Sanofi Collaboration Revenue	Six Months Ended June 30,	
(In millions)	2016	2015
Antibody:		
Reimbursement of Regeneron research and development expenses	$337.8	$380.3
Reimbursement of Regeneron commercialization-related expenses	159.2	35.8
Regeneron's share of losses in connection with commercialization of antibodies	(221.5)	(68.7)
Other	6.0	5.1
Total Antibody	281.5	352.5
Immuno-oncology:		
Reimbursement of Regeneron research and development expenses	61.6	—
Other	40.0	—
Total Immuno-oncology	101.6	—
ZALTRAP:		
Reimbursement of Regeneron research and development expenses	—	0.7
Other	—	15.2
Total ZALTRAP	—	15.9
Total Sanofi collaboration revenue	$383.1	$368.4

In the first half of 2016, Sanofi's reimbursement of our antibody research and development expenses consisted of $105.6 million under our Antibody Discovery Agreement and $232.2 million under our License and Collaboration Agreement, compared to $102.4 million and $277.9 million, respectively, in the first half of 2015. The lower reimbursement of research and development costs in the first half of 2016, compared to the same period in 2015, was primarily due to decreased development activities for Praluent and the fact that in 2016, Sanofi no longer co-develops and reimburses us for development activities for REGN1033 and REGN2222. These decreases were partly offset by increased development activities for dupilumab.

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

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During the six months ended June 30, 2015, we and Sanofi shared pre-launch commercial expenses related to Praluent and sarilumab in accordance with the companies' License and Collaboration Agreement. In addition, effective in the first quarter of 2016, we and Sanofi also began sharing pre-launch commercialization expenses related to dupilumab. As such, we recorded our share of losses in connection with preparing to commercialize Praluent, sarilumab, and dupilumab within Sanofi collaboration revenue. Commencing in the third quarter of 2015, after regulatory approval was received, we also recorded within Sanofi collaboration revenue our share of the Antibody Collaboration's losses in connection with commercialization of Praluent. We and Sanofi incurred higher commercialization expenses for Praluent in the first half of 2016, compared to the same period in 2015, primarily in connection with launching the product in the United States and certain European countries. Praluent net product sales, which are recorded by Sanofi, were $37.4 million in the first half of 2016.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology. In the first half of 2016, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $42.7 million under our IO Discovery Agreement, and $18.9 million under our IO License and Collaboration Agreement related to REGN2810. Other Sanofi immuno-oncology revenue includes recognition of deferred revenue from $640.0 million of up-front payments received in the third quarter of 2015 in connection with the execution of the IO Collaboration agreements.

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

Bayer Collaboration Revenue

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

Bayer Collaboration Revenue	Six Months Ended June 30,	
(In millions)	2016	2015
EYLEA:		
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$313.3	$196.1
Sales milestones	—	15.0
Cost-sharing of Regeneron EYLEA development expenses	5.0	5.1
Other	39.8	29.5
Total EYLEA	358.1	245.7
PDGFR-beta antibody:		
Cost-sharing of REGN2176-3 development expenses	4.7	7.2
Other	5.2	5.2
Total PDGFR-beta antibody	9.9	12.4
Ang2 antibody:		
Cost-sharing of nesvacumab/aflibercept (REGN910-3) development expenses	2.1	—
Other	1.4	—
Total Ang2 antibody	3.5	—
Total Bayer collaboration revenue	$371.5	$258.1

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	Six Months Ended June 30,	
(In millions)	2016	2015
Net product sales outside the United States	$905.1	$629.6
Regeneron's share of collaboration profit from sales outside the United States	340.4	223.9
Reimbursement of EYLEA development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(27.1)	(27.8)
Regeneron's net profit in connection with commercialization of EYLEA outside the United States	$313.3	$196.1

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

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

Bayer is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer made a $5.0 million development milestone payment to us in the second quarter of 2015, which was recognized as revenue in the quarter and included in "Cost-sharing of REGN2176-3 development expenses" in the table above.

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

Other Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the first half of both 2016 and 2015, we recognized $11.8 million of revenue related to this agreement.

In connection with the February 2015 Amended ZALTRAP Agreement, we recorded $14.6 million of revenue in the first half of 2016 primarily related to (i) a percentage of net sales of ZALTRAP for the quarter that Sanofi is obligated to pay us and (ii) manufacturing ZALTRAP commercial supplies for Sanofi. In the first half of 2015, we recorded $23.0 million of revenue in connection with the Amended ZALTRAP Agreement primarily related to (i) manufacturing ZALTRAP commercial supplies for Sanofi and (ii) a percentage of net sales of ZALTRAP from July 1, 2014 (the effective date of the Amended ZALTRAP Agreement) through June 30, 2015.

Expenses

Total operating expenses increased to $1,792.5 million in the first half of 2016 from $1,239.8 million in the first half of 2015. Our average headcount in the first half of 2016 increased to 4,615 from 3,320 in the same period in 2015, principally in connection with expanding our research and development, manufacturing, and commercialization activities.

Operating expenses in the first half of 2016 and 2015 included a total of $273.9 million and $198.0 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 half of 2016 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2015 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $1,030.0 million in the first half of 2016 from $733.4 million in the same period of 2015. The following table summarizes the major categories of our research and development expenses:

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Research and Development Expenses (In millions)	Six Months Ended June 30, 2016	2015	Increase (Decrease)
Payroll and benefits [1]	$300.9	$236.7	$ 64.2
Clinical trial expenses	172.3	131.0	41.3
Clinical manufacturing costs [2]	264.2	184.9	79.3
Research and other development costs	153.2	65.2	88.0
Occupancy and other operating costs	85.8	64.1	21.7
Cost-sharing of Bayer and Sanofi development expenses [3]	53.6	51.5	2.1
Total research and development expenses	$1,030.0	$733.4	$ 296.6

[1] Includes Non-cash Compensation Expense of $133.0 million for the six months ended June 30, 2016 and $101.4 million for the six months ended June 30, 2015.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer, New York manufacturing facility. Also includes Non-cash Compensation Expense of $24.4 million for the six months ended June 30, 2016 and $18.1 million for the six months ended June 30, 2015.

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

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased primarily due to (i) the initiation of additional clinical studies of fasinumab and (ii) additional enrollment in REGN2810 clinical studies as well as the initiation of a clinical study in REGN2810 for the treatment of advanced cutaneous squamous cell carcinoma. Clinical manufacturing costs increased primarily due to costs related to manufacturing additional drug supplies of dupilumab, fasinumab, REGN2222, and REGN2810, partly offset by costs related to manufacturing less clinical supplies of Praluent. Research and other development costs increased primarily due to the $75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia. Occupancy and other operating costs increased principally in connection with higher information technology- and facility-related costs at our Tarrytown and Rensselaer, New York sites due to higher headcount and expanded research and development activities.

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

Project Costs	Six Months Ended June 30,		Increase
(In millions)	2016	2015	(Decrease)
Praluent	$82.0	$131.2	$ (49.2)
Dupilumab	238.1	167.6	70.5
Sarilumab	27.2	38.2	(11.0)
Fasinumab	79.7	9.5	70.2
REGN2222	34.9	16.8	18.1
REGN2810	44.0	12.8	31.2
Other antibody candidates in clinical development	104.8	121.4	(16.6)
Other research programs and unallocated costs [(1)]	419.3	235.9	183.4
Total research and development expenses	$1,030.0	$733.4	$ 296.6

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

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

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to $581.7 million in the first half of 2016 from $333.6 million in the first half of 2015 primarily due to (i) higher commercialization-related expenses associated with EYLEA and Praluent, (ii) higher contributions to not-for-profit organizations, including donations to independent not-for-profit patient assistance organizations, (iii) higher headcount and headcount-related costs, and (iv) higher Non-cash Compensation Expense principally for the reason described under "Expenses" above. Selling, general, and administrative expenses included $107.8 million and $74.3 million of Non-cash Compensation Expense in the first half of 2016 and 2015, respectively.

Cost of Goods Sold

Cost of goods sold was $120.2 million in the first half of 2016 and $103.4 million in the first half of 2015. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold increased principally due to an increase in Limerick start-up costs and the increase in U.S. EYLEA net sales. These increases were partly offset by the fact that, effective May 2016, we are no longer obligated to pay royalties to Genentech based on sales of EYLEA. In addition, in the first half of 2016 and 2015, cost of goods sold included inventory write-downs and reserves totaling $6.3 million and $8.1 million, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer, decreased to $60.6 million in the first half of 2016 from $69.4 million in the first half of 2015. This decrease was primarily due to recognizing as expense $20.2 million of inventoried costs for ZALTRAP commercial supplies in the first half of 2015 that were previously shipped to Sanofi because our risk of inventory loss no longer existed under the Amended ZALTRAP Agreement, partly offset by the recognition of costs

associated with commercial supplies of ZALTRAP shipped to Sanofi in the first half of 2016.

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Other Income and Expense

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

Income Taxes

In the first half of 2016 and 2015, we recorded income tax expense of $244.8 million and $333.9 million, respectively. The effective tax rate was 39.3% and 55.2% for the first half of 2016 and 2015, respectively. The effective tax rate for the first half of 2016 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee, partly offset by the positive impact of the tax benefit associated with stock-based compensation, the domestic manufacturing deduction, the federal tax credit for increased research activities.

The effective tax rate for the first half of 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-tax deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities.

Liquidity and Capital Resources

Sources and Uses of Cash for the Six Months Ended June 30, 2016 and 2015

As of June 30, 2016, we had $1,635.0 million in cash, cash equivalents, and marketable securities compared with $1,677.4 million as of December 31, 2015. Additionally, as of June 30, 2016, we had borrowing availability of $750.0 million under a revolving credit facility that was entered into during the first quarter of 2015 (see further description under "Credit Facility" below).

Cash Provided by Operating Activities

Net cash provided by operating activities was $444.5 million in the first half of 2016. Our net income of $377.6 million in the first half of 2016 included Non-cash Compensation Expense of $273.9 million, depreciation and amortization of $48.0 million, and the $75.0 million up-front payment made in connection with the April 2016 license and collaboration agreement with Intellia. In addition, deferred tax assets as of June 30, 2016 increased by $162.7 million, compared to December 31, 2015, primarily due to an increase in share-based compensation and deferred revenue.

As of June 30, 2016, Sanofi, Bayer, and trade accounts receivable increased by $284.2 million, compared to December 31, 2015, primarily due to higher U.S. EYLEA sales. Inventories as of June 30, 2016 increased by $72.9 million, compared to December 31, 2015, primarily due to increased production of commercial supplies of EYLEA and Praluent. Prepaid expenses and other assets decreased by $57.1 million as of June 30, 2016, compared to December 31, 2015, primarily due to a decrease in prepaid income taxes. Deferred revenue increased by $65.9 million as of June 30, 2016, compared to December 31, 2015, primarily due to $60.0 million of payments received in 2016 from Mitsubishi in connection with the companies' fasinumab Asia collaboration and the $50.0 million up-front payment from Bayer (as described above), partly offset by the amortization of up-front payments from Sanofi. Accounts payable, accrued expenses, and other liabilities increased by $133.9 million as of June 30, 2016, compared to December 31, 2015, primarily due to higher tax-related liabilities.

Net cash provided by operating activities was $156.1 million in the first half of 2015. Our net income of $270.7 million in the first half of 2015 included Non-cash Compensation Expense of $198.0 million and depreciation and amortization of $31.3 million. In addition, deferred tax assets as of June 30, 2015 increased by $59.1 million, compared to December 31, 2014, primarily due to an increase in Non-cash Compensation Expense, partly offset by a reduction in deferred revenue.

As of June 30, 2015, Sanofi, Bayer, and trade accounts receivable increased by $418.8 million, compared to December 31, 2014, primarily due to higher U.S. EYLEA sales and higher amounts due from Sanofi in connection with the companies' Antibody Collaboration. Inventories as of June 30, 2015 increased by $45.6 million, compared to December 31, 2014, primarily due to increased production of EYLEA commercial supplies. Accounts payable,

accrued expenses, and other liabilities increased by $129.3 million as of June 30, 2015, compared to December 31, 2014, primarily due to (i) higher accruals for sales-related charges (including the impact of the Branded Prescription Drug Fee) and deductions, and royalties related to EYLEA, and (ii) higher expenditures in connection with our expanding research and development activities.

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Cash Used in Investing Activities

Net cash used in investing activities was $369.7 million and $501.1 million in the first half of 2016 and 2015, respectively. In the first half of 2016 and 2015, purchases of marketable securities exceeded sales or maturities by $126.8 million and $147.1 million, respectively. Capital expenditures were $242.9 million and $354.1 million in the first half of 2016 and 2015, respectively. Capital expenditures in the first half of 2016 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility, tenant improvement and associated costs at our leased Tarrytown, New York facilities, renovations to certain areas of our Rensselaer, New York manufacturing facilities, the purchase of an office building near our Rensselaer manufacturing facilities, and purchases of equipment. Capital expenditures in the first half of 2015 primarily included costs in connection with renovations of our Limerick, Ireland manufacturing facility and tenant improvement and associated costs related to two new buildings which were under construction at our leased Tarrytown, New York facilities. In addition, in April 2015, we acquired an approximate 100-acre parcel of undeveloped land adjacent to our current Tarrytown, New York Location for an aggregate purchase price of $73.0 million.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $237.4 million in the first half of 2016 and net cash provided by financing activities was $86.9 million in the first half of 2015. In the first half of 2015, proceeds in connection with facility and capital leases obligations primarily relates to reimbursements of $27.4 million we received from our landlord for tenant improvement costs in connection with our leased facilities in Tarrytown, New York. In the first half of 2016 and 2015, $12.7 million and $144.0 million principal amount of our Notes, respectively, that was previously surrendered for conversion was settled. In accordance with the terms of the Notes, we elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of our Common Stock in respect of any amounts due in excess thereof. Also during the first half of 2016 and 2015, we paid an aggregate amount of $242.1 million and $124.5 million, respectively, to warrant holders to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants. Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $63.6 million in the first half of 2016, compared to $115.8 million in the first half of 2015. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted stock (as applicable) were $45.0 million in the first half of 2016 compared to $35.9 million in the first half of 2015. In the first half of 2015, cash flows from financing activities included $248.7 million, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations. In the second quarter of 2016, we elected to adopt Accounting Standards Update 2016-09, Compensation - Stock Compensation, Improvements to Employee Share-Based Payment Accounting. As a result, we prospectively recorded excess tax benefits as an operating activity in the statement of cash flows (previously, such amounts were recognized as a financing activity in the statement of cash flows).

Credit Facility

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a $750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of June 30, 2016.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Credit

Facility as of June 30, 2016.

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Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $242.9 million in the first half of 2016 and $354.1 million in the first half of 2015 (as described under "Cash Used in Investing Activities" above). We expect to incur capital expenditures of approximately $237 million to $287 million in the second half of 2016 primarily in connection with renovating our new Limerick, Ireland facility, expanding and renovating portions of our Tarrytown, New York facilities, and expanding and renovating portions of our manufacturing facilities at our Rensselaer, New York facility.

Funding Requirements

We believe that our existing capital resources, borrowing availability under our revolving credit facility, funds generated by anticipated EYLEA net product sales, and, as described above under "Collaboration Agreements," funding for reimbursement of research and development costs that we are entitled to receive under our collaboration agreements with Sanofi and Bayer, will enable us to meet our projected operating needs for the foreseeable future.

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

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

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

We enter into research collaboration and licensing agreements that may require us to pay (i) amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant, and/or (ii) royalties calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted. For example, we are obligated to pay Sanofi up to $20.0 million in potential additional development milestones in connection with our PDGFR-beta antibody clinical program.

From time to time, we may seek to reduce the number of warrants outstanding through additional amendment agreements with warrant holders or otherwise.

As of June 30, 2016, an aggregate principal amount of $0.2 million of our Notes remained outstanding, which mature on October 1, 2016, unless earlier converted or repurchased.

Future Impact of Recently Issued Accounting Standards

See Note 13 to our Condensed Consolidated Financial Statements for a summary of recently issued accounting standards.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures Around Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (filed February 11, 2016). There have been no material changes to our market risks or to our management of such risks as of June 30, 2016.

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ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business, including those described in our Annual Report on Form 10-K for the year ended December 31, 2015 (filed February 11, 2016), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016 (filed May 5, 2016), and those described below. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see Part II, Item 1A. "Risk Factors," including the discussion under the headings entitled "Risks Related to Intellectual Property and Market Exclusivity," "Regulatory and Litigation Risks," and "Risks Related to Our Common Stock."

Proceedings Relating to '287 Patent and '163 Patent

As previously reported, on September 25, 2013, we commenced patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting our European Patent No. 1,360,287 (the '287 Patent) and European Patent No. 2,264,163 (the '163 Patent), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. A trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent was held from November 16, 2015 through December 8, 2015. On February 1, 2016, the court issued a final judgment, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. On April 27, 2016, the court granted permission for our appeal and Kymab's cross-appeal, and on May 18, 2016, Regeneron and Kymab filed their respective notices to appeal the court's decision on the '287 and '163 Patents. The appeal and the cross-appeal are expected to be heard together.

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

Proceedings Relating to Praluent (alirocumab) Injection

As previously reported, we are currently a party to a patent infringement action initiated by Amgen Inc. against us and Sanofi relating to Praluent, which we are jointly developing and commercializing with Sanofi. In this action, Amgen asserted a number of U.S. patents, which were subsequently narrowed to U.S. Patent Nos. 8,829,165 (the '165 Patent) and 8,859,741 (the '741 Patent).

As previously reported, a jury trial and a permanent injunction hearing in this litigation were held in March 2016. During the course of the trial, the court ruled as a matter of law in favor of Amgen that the asserted patent claims were not obvious, and in favor of Regeneron and Sanofi that there was no willful infringement of the asserted patent claims by Regeneron or Sanofi. On March 16, 2016, the jury returned a verdict in favor of Amgen, finding that the asserted claims of the '165 and '741 Patents were not invalid based on either a lack of written description or a lack of enablement. The parties to this litigation submitted post-trial briefs in the second quarter of 2016 and are awaiting the

court's final opinion and judgment, including a decision on the permanent injunction. We and Sanofi plan to appeal any judgment or order that is adverse to us and Sanofi.

On July 25, 2016, Amgen filed a lawsuit against us, Sanofi-Aventis Groupe S.A., Sanofi-Synthelabo Limited, Aventis Pharma Limited, Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the English High Court of Justice, Chancery Division, Patents Court, in London, seeking a declaration of infringement of Amgen's European Patent No. 2,215,124 (the '124

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Patent), which pertains to PCSK9 monoclonal antibodies, by Praluent. The lawsuit also seeks an injunction, damages, an accounting of profits, and costs and interest. We have not yet been served with the documents relating to the lawsuit.

Also on July 25, 2016, Amgen filed a lawsuit for infringement of the '124 Patent against us, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A., and Sanofi-Aventis Deutschland GmbH in the Regional Court of Düsseldorf, Germany, seeking an injunction, an accounting of marketing activities, a recall of Praluent and its removal from the distribution channels, and damages. We have not yet been served with the documents relating to the lawsuit.

Proceedings Relating to Patents Owned by Genentech and City of Hope

As previously reported, on July 27, 2015, we and Sanofi-Aventis U.S. LLC filed a complaint in the United States District Court for the Central District of California (Western Division) seeking a declaratory judgment of invalidity, as well as non-infringement by the manufacture, use, sale, offer of sale, or importation of Praluent, of U.S. Patent No. 7,923,221 jointly owned by Genentech, Inc. and City of Hope relating to the production of recombinant antibodies by host cells. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016 (subsequently vacated as noted below). On July 18, 2016, the court vacated the trial commencement date of September 27 in light of other pending motions.

Proceedings Relating to Shareholder Derivative Claim

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

ITEM 1A. RISK FACTORS

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

Risks Related to Commercialization of EYLEA

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

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the six months ended June 30, 2016 and 2015, EYLEA net sales in the United States represented 67% and 64% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

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

- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
-

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

- our ability to meet the demand for commercial supplies of EYLEA;

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- our ability to differentiate EYLEA from Lucentis® (ranibizumab) and other competitive products, and the willingness of retinal specialists and patients to switch from Lucentis or off-label use of repackaged Avastin® (bevacizumab) to EYLEA or to start treatment with EYLEA;
- the ability of patients, retinal specialists, and other providers to obtain and maintain sufficient coverage and reimbursement from third-party payers, including Medicare and Medicaid in the United States and other government and private payers in the United States and foreign jurisdictions;
- our ability to maintain sales of EYLEA in the face of competitive products, including those currently in clinical development;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices; and
- risks associated with intellectual property of other parties and pending or future litigation relating thereto, as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below.

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

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

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

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

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

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

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

The commercial success of EYLEA is subject to strong competition.

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

Other competitive or potentially competitive products include Allergan plc's Ozurdex® (dexamethasone intravitreal implant) (approved by the FDA in June 2009 for the treatment of macular edema following RVO and in September 2014 for the treatment of DME) and Alimera Sciences' Iluvien® (fluocinolone acetonide intravitreal implant) (approved by the FDA in September 2014 for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure), both of which are intravitreal implants of corticosteroids. Many other companies are working on the development of product candidates and extended delivery devices for the potential treatment of wet AMD, DME, and RVO, including those that act by blocking VEGF and VEGF receptors, as well as small interfering ribonucleic acids (siRNAs) that modulate gene

expression. For example, Genentech/Roche is developing a Lucentis port delivery system implant (currently in a Phase 2 study in patients with wet AMD). Novartis is developing RTH258 (ESBA1008), a humanized monoclonal single-chain FV (scFv) antibody fragment targeting VEGF-A for wet AMD, and initiated a non-inferiority Phase 3 trial comparing RTH258 and EYLEA in December 2014. Allergan is developing abicipar pegol (an anti-VEGF-A DARPin®) for wet AMD and related conditions (currently studied in Phase 3 trials against Lucentis as a comparator drug). Additionally, companies are developing products (or combinations of products) to treat wet AMD that act by blocking VEGF and VEGF receptors, as well as other targets (for example, PDGF). Ophthotech Corporation (in collaboration with Novartis) is developing Fovista®, an aptamer directed against platelet-derived growth factor subunit B (PDGF-B), as a product candidate intended to be used in combination with an anti-VEGF therapy in wet AMD. In 2013, Ophthotech initiated Phase 3 trials in AMD evaluating multiple combinations of Fovista, including Lucentis + Fovista, Avastin + Fovista, and EYLEA + Fovista. Genentech/Roche is developing a bi-specific antibody targeting both VEGF and Ang2 for wet AMD and DME (currently in Phase 2 trials for both indications). Competitors are also developing eye-drop formulations, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

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

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

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

We rely on our collaboration with Bayer for commercializing EYLEA.

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

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

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

Our sales of EYLEA in the United States and Bayer's sales of EYLEA in other countries may be reduced if EYLEA is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet) take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. Prices for EYLEA in territories outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices

for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and our sales of EYLEA in the United States may be reduced if EYLEA marketed in those nations is imported into the United States. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of EYLEA in a particular market or reduce our or Bayer's sales, thereby adversely affecting our results of operations. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues derived from EYLEA sales could be reduced.

Risks Related to Commercialization of Praluent

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

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

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

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

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

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

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

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

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

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

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

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

The commercial success of Praluent is subject to strong competition.

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

by Esperion Therapeutics, Inc.

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and

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

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

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

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

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

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our company, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. For example, a randomized, double-blind Phase 3 trial (VENICE) that evaluated ZALTRAP as a first-line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone did not meet the pre-specified criterion of improvement in overall survival in April 2011. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

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

recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

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

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

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

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

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

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

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

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

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

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

Some of our products