REGENERON PHARMACEUTICALS INC
Form 10-Q
November 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 September 30, 2016

OR

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

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

(914) 847-7000

(Registrant's telephone number, including area code)

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

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

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

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

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

Number of shares outstanding of each of the registrant's classes of common stock as of October 20, 2016:

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

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QUARTERLY REPORT ON FORM 10-Q
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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)

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

| | | |
|---|---|---|
| Accumulated other comprehensive (loss) income | (2,899) | 8,572 |
| Treasury stock, at cost; 3,761,628 shares in 2016 and 3,642,820 in 2015 | (316,052) | (306,069) |
| Total stockholders' equity | 4,491,247 | 3,654,837 |
| Total liabilities and stockholders' equity | $6,828,019 | $5,609,132 |

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

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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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Statements of Operations | | | | |
| Revenues: | | | | |
| Net product sales | $857,468 | $737,562 | $2,475,869 | $1,939,954 |
| Sanofi collaboration revenue | 144,392 | 224,735 | 527,500 | 593,201 |
| Bayer collaboration revenue | 191,298 | 157,596 | 562,786 | 415,679 |
| Other revenue | 26,964 | 17,529 | 67,445 | 56,817 |
| | 1,220,122 | 1,137,422 | 3,633,600 | 3,005,651 |
| Expenses: | | | | |
| Research and development | 543,047 | 425,924 | 1,573,089 | 1,159,367 |
| Selling, general, and administrative | 270,045 | 209,993 | 851,760 | 543,572 |
| Cost of goods sold | 29,901 | 67,199 | 150,090 | 170,624 |
| Cost of collaboration and contract manufacturing | 14,327 | 41,884 | 74,923 | 111,254 |
| | 857,320 | 745,000 | 2,649,862 | 1,984,817 |
| Income from operations | 362,802 | 392,422 | 983,738 | 1,020,834 |
| Other income (expense): | | | | |
| Investment income | 3,301 | 2,140 | 8,351 | 3,973 |
| Interest and other expense, net | (222) | (1,273) | (3,801) | (26,999) |
| | 3,079 | 867 | 4,550 | (23,026) |
| Income before income taxes | 365,881 | 393,289 | 988,288 | 997,808 |
| Income tax expense | (101,077) | (182,891) | (345,881) | (516,746) |
| Net income | $264,804 | $210,398 | $642,407 | $481,062 |
| Net income per share - basic | $2.53 | $2.04 | $6.14 | $4.68 |
| Net income per share - diluted | $2.27 | $1.82 | $5.51 | $4.18 |
| Weighted average shares outstanding - basic | 104,833 | 103,348 | 104,586 | 102,825 |
| Weighted average shares outstanding - diluted | 116,466 | 115,944 | 116,567 | 115,144 |
| Statements of Comprehensive Income | | | | |
| Net income | $264,804 | $210,398 | $642,407 | $481,062 |
| Other comprehensive income (loss): | | | | |
| Unrealized loss on marketable securities, net of tax | (8,103) | (11,432) | (11,471) | (44,530) |
| Comprehensive income | $256,701 | $198,966 | $630,936 | $436,532 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| Cash flows from operating activities: | | |
| Net income | $ 642,407 | $ 481,062 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 75,845 | 51,999 |
| Non-cash compensation expense | 405,320 | 300,657 |
| Other non-cash charges and expenses, net | 13,586 | 34,919 |
| Deferred taxes | (190,327) | (65,975) |
| Changes in assets and liabilities: | | |
| Increase in Sanofi, Bayer, and trade accounts receivable | (176,079) | (462,943) |
| Increase in inventories | (99,706) | (66,254) |
| Decrease (increase) in prepaid expenses and other assets | 34,857 | (13,223) |
| Increase in deferred revenue | 282,176 | 624,063 |
| Increase in accounts payable, accrued expenses, and other liabilities | 107,438 | 164,652 |
| Total adjustments | 453,110 | 567,895 |
| Net cash provided by operating activities | 1,095,517 | 1,048,957 |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (606,153) | (550,142) |
| Sales or maturities of marketable securities | 192,091 | 265,995 |
| Capital expenditures | (361,486) | (500,154) |

| | | |
|---|---|---|
| Net cash used in investing activities | (775,548) | (784,301) |
| Cash flows from financing activities: | | |
| Proceeds in connection with facility lease obligations | 3,232 | 26,405 |
| Repayments of convertible senior notes | (12,650) | (146,007) |
| Payments in connection with reduction of outstanding warrants | (242,117) | (523,487) |
| Proceeds from issuance of Common Stock | 89,777 | 150,423 |
| Payments in connection with Common Stock tendered for employee tax obligations | (46,954) | (71,673) |
| Excess tax benefit from stock-based compensation | — | 305,551 |
| Net cash used in financing activities | (208,712) | (258,788) |
| Net increase in cash and cash equivalents | 111,257 | 5,868 |
| Cash and cash equivalents at beginning of period | 809,102 | 648,719 |
| Cash and cash equivalents at end of period | $ 920,359 | $ 654,587 |

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

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

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the nine months ended September 30, 2016 and 2015.

| | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2015 | $ 6,419 | $ 48,313 | $ 517 | $55,249 |
| Provision related to current period sales | 63,510 | 113,755 | 22,812 | 200,077 |
| Credits/payments | (62,503) | (135,483) | (19,587) | (217,573) |
| Balance as of September 30, 2016 | $ 7,426 | $ 26,585 | $ 3,742 | $37,753 |
| | | | | |
| Balance as of December 31, 2014 | $ 3,083 | $ 21,166 | $ 532 | $24,781 |
| Provision related to current period sales | 41,290 | 88,049 | 6,024 | 135,363 |
| Credits/payments | (38,011) | (71,007) | (6,052) | (115,070) |
| Balance as of September 30, 2015 | $ 6,362 | $ 38,208 | $ 504 | $45,074 |

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

3. Collaboration Agreements

a. Sanofi

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

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

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

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

Antibodies

In November 2007, the Company entered into a global, strategic collaboration with Sanofi to discover, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"). The Antibody Collaboration is governed by the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and a License and Collaboration Agreement (each as amended). Pursuant to the Antibody Discovery Agreement, Sanofi is obligated to fund up to $130.0 million of the Company's research activities in 2016. Under the License and Collaboration Agreement, agreed-upon worldwide development expenses incurred by both companies are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. During the three months ended September 30, 2016 and 2015, the Company recognized as additional research and development expense $27.9 million and $25.1 million, respectively, and during the nine months ended September 30, 2016 and 2015, the Company recognized as additional research and development expense $80.2 million and $72.6 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent®, sarilumab, and, commencing in the first quarter of 2016, Dupixent® (dupilumab).

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

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

Immuno-Oncology

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

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

ZALTRAP

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

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

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

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

b. Bayer

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

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

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

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

EYLEA outside the United States

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

PDGFR-beta antibody outside the United States

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

Ang2 antibody outside the United States

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

United States, the Company has exclusive commercialization rights and will retain all of the profits from sales.

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

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

c. Mitsubishi Tanabe Pharma

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

d. Teva

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

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

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

e. Intellia Therapeutics

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

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

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

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

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

f. Adicet Bio

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

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

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

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4. Net Income Per Share

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

| | Three Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| Net income - basic | $264,804 | $210,398 |
| Effect of dilutive securities: | | |
| Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs | — | 145 |
| Net income - diluted | $264,804 | $210,543 |
| | | |
| (Shares in thousands) | | |
| Weighted average shares - basic | 104,833 | 103,348 |
| Effect of dilutive securities: | | |
| Stock options | 10,156 | 9,632 |
| Restricted stock | 479 | 481 |
| Convertible senior notes | — | 308 |
| Warrants | 998 | 2,175 |
| Dilutive potential shares | 11,633 | 12,596 |
| Weighted average shares - diluted | 116,466 | 115,944 |
| | | |
| Net income per share - basic | $2.53 | $2.04 |
| Net income per share - diluted | $2.27 | $1.82 |

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

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

| | Three Months Ended September 30, | |
|---|---|---|
| (Shares in thousands) | 2016 | 2015 |
| Stock options | 7,687 | 594 |
| Restricted stock | 19 | — |
| Convertible senior notes | 3 | — |

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

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5. Marketable Securities

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

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

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

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

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

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

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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 September 30, 2016 | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss |
| Unrestricted | | | | | | |
| Corporate bonds | $354,112 | $(475) | $52,787 | $ (86) | $406,899 | $(561) |
| U.S. government and government agency obligations | 29,200 | (40) | — | — | 29,200 | (40) |
| Municipal bonds | 1,529 | (1) | — | — | 1,529 | (1) |
| Equity securities | 7,435 | (7,565) | — | — | 7,435 | (7,565) |
| | 392,276 | (8,081) | 52,787 | (86) | 445,063 | (8,167) |
| Restricted | | | | | | |
| Equity securities | 44,157 | (5,843) | — | — | 44,157 | (5,843) |
| | $436,433 | $(13,924) | $52,787 | $ (86) | $489,220 | $(14,010) |
| | | | | | | |
| As of December 31, 2015 | | | | | | |
| Corporate bonds | $668,199 | $(2,473) | $23,749 | $ (92) | $691,948 | $(2,565) |
| U.S. government and government agency obligations | 51,215 | (193) | — | — | 51,215 | (193) |
| Municipal bonds | 11,917 | (11) | — | — | 11,917 | (11) |
| | $731,331 | $(2,677) | $23,749 | $ (92) | $755,080 | $(2,769) |

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

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

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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 September 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 | $967,921 | — | $967,921 |
| U.S. government and government agency obligations | 116,096 | — | 116,096 |
| Municipal bonds | 10,225 | — | 10,225 |
| Commercial paper | 73,419 | — | 73,419 |
| Certificates of deposit | 36,056 | — | 36,056 |
| Equity securities | 18,064 | $18,064 | — |
| | 1,221,781 | 18,064 | 1,203,717 |
| Restricted | | | |
| Equity securities | 44,157 | — | 44,157 |
| | $1,265,938 | $18,064 | $1,247,874 |
| | | | |
| As of December 31, 2015 | | | |
| Available-for-sale marketable securities: | | | |
| Unrestricted | | | |
| Corporate bonds | $767,683 | — | $767,683 |
| U.S. government and government agency obligations | 51,209 | — | 51,209 |
| Municipal bonds | 17,924 | — | 17,924 |
| Equity securities | 31,467 | $31,467 | — |
| | $868,283 | $31,467 | $836,816 |

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

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

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

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

7. Inventories

Inventories consist of the following:

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

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

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

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

9. Debt

a. Convertible Debt

In the first nine months of 2016, the Company settled conversion obligations for $12.7 million principal amount of the Company's Notes that was previously surrendered for conversion. Consequently, in the first nine months of 2016, the Company paid $12.7 million in cash and issued 118,822 shares of Common Stock. In addition, the Company allocated $47.1 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholder's equity. The loss on the debt extinguishment in connection with the Notes that were surrendered for

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conversion during the first nine months of 2016 was not material. As a result of these Note conversions, in the first nine months of 2016, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 118,808 shares of Common Stock, which was approximately equal to the number of shares the Company was required to issue to settle the non-cash portion of the related Note conversions. The Company recorded the cost of the shares received, or $10.0 million, as Treasury Stock during the first nine months of 2016.

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

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

Warrant Transactions

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

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

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

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $397.75

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

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

b. Credit Facility

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

10. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of $101.1 million and $182.9 million for the three months ended September 30, 2016 and 2015, respectively, and $345.9 million and $516.7 million for the nine months ended September 30, 2016 and 2015, respectively. The Company's effective tax rate was 27.6% and 46.5% for the three months ended September 30, 2016 and 2015, respectively, and 35.0% and 51.8% for the nine months ended September 30, 2016 and 2015, respectively. The Company's effective tax rate for the three and nine months ended September 30, 2016 was positively impacted, compared to the U.S. federal statutory rate, by the tax benefit associated with stock-based compensation (see Note 13), the domestic manufacturing deduction, and the federal tax credit for increased research activities, offset by the negative impact of losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate and the non-tax deductible Branded Prescription Drug Fee. The Company's effective tax rate for the three months ended September 30, 2016 was also positively impacted by changes to tax reserves.

The Company's effective tax rate for the three and nine months ended September 30, 2015 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, the non-deductible Branded Prescription Drug Fee, and expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

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

11. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

Included in accounts payable and accrued expenses as of September 30, 2016 and December 31, 2015 were $33.9 million and $50.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses as of September 30, 2015 and December 31, 2014 were $84.7 million and $56.2 million, respectively, of accrued capital expenditures.

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

Included in accounts payable and accrued expenses as of December 31, 2014 was $59.8 million related to the Company's payment obligation for a reduction in the number of warrants based on a warrant holder closing out a portion of its hedge position. Additionally, included within other current liabilities as of December 31, 2014 was $87.5

million in connection with the estimated fair value of the remaining warrant liability. There were no such liabilities recorded in connection with warrants as of September 30, 2016, December 31, 2015, and September 30, 2015.
The Company recognized an additional facility lease obligation of $16.4 million and $27.0 million during the nine months ended September 30, 2016 and 2015, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

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12. Legal Matters

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

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

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

Proceedings Relating to Praluent (alirocumab) Injection

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

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

and Sanofi plan to appeal any judgment or order that is adverse to the Company and Sanofi.

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

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

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

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

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

Proceedings Relating to Patents Owned by Genentech and City of Hope

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

Proceedings Relating to Shareholder Derivative Claims

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

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

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

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

13. Recently Issued Accounting Standards

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

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

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

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

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

Overview

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

Our total revenues were $1,220.1 million in the third quarter and $3,633.6 million in the first nine months of 2016, compared to $1,137.4 million in the third quarter and $3,005.7 million in the first nine months of 2015. Our net income was $264.8 million, or $2.27 per diluted share, in the third quarter and $642.4 million, or $5.51 per diluted share, in the first nine months of 2016, compared to net income of $210.4 million, or $1.82 per diluted share, in the third quarter and $481.1 million, or $4.18 per diluted share, in the first nine months of 2015. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

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

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

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

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| combination with REGN1979 in B-cell malignancies. | |
| REGN3500 | Antibody to an undisclosed target being developed for inflammatory diseases. Phase 1 study in healthy volunteers initiated in the third quarter of 2016. |
| Antibody-based Clinical Program in Collaboration with Bayer | |
| Rinucumab/aflibercept (REGN2176-3)** | Combination product comprised of an antibody to PDGFR-beta co-formulated with aflibercept for intravitreal injection for use in ophthalmology. The Phase 2 study in wet AMD did not meet its primary endpoint. |
| Nesvacumab/aflibercept (REGN910-3)** | Combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology. Phase 2 studies for the treatment of wet AMD and DME initiated in the first quarter of 2016. Fast track designation received from the FDA for the treatment of patients with wet AMD, DME, and diabetic retinopathy. |

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| Antibody-based Clinical Program in Collaboration with Teva and Mitsubishi Tanabe Pharma | |
| Fasinumab (REGN475)* | Antibody to Nerve Growth Factor (NGF). Phase 3 long-term safety and efficacy study in patients with osteoarthritis of knee and hip initiated in the first quarter of 2016. Phase 2b study for chronic low back pain initiated in the first quarter of 2016, and placed on clinical hold by the FDA in October 2016. |
| Antibody-based Clinical Programs Developing Independently | |
| REGN2222* | Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. In Phase 3 clinical development for prevention of RSV infection. |
| Evinacumab (REGN1500)* | Antibody to Angptl-3. In Phase 1/2 clinical development for the treatment of homozygous familial hypercholesterolemia (HoFH) and severe forms of hyperlipidemia. |
| Trevogrumab (REGN1033)* | Antibody to myostatin (GDF8). Phase 2 monotherapy clinical |

development in skeletal muscle disorders completed. Combination therapy plans are in development.

REGN1908-1909* Antibody to Feld1. In Phase 1 clinical development against allergic disease.

REGN1979 Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, and Acute Lymphoblastic Leukemia. REGN1979 is also being studied in combination with REGN2810 in B-cell malignancies.

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

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

* Sanofi did not opt-in to or elected not to continue to co-develop the product

candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on any future sales of the product candidate.

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

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

We believe that our ability to develop product candidates is enhanced by the application of our VelociSuite® technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified

mice using our VelociGene® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (VelocImmune) and cell line expression technologies (VelociMab®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using VelocImmune. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

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Marketed Products

EYLEA (aflibercept) Injection

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

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

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

Praluent (alirocumab) Injection

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

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

ARCALYST (rilonacept) Injection for Subcutaneous Use

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

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

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Clinical Programs - Ophthalmologic Diseases

EYLEA - Ophthalmologic Diseases

Overview

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

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

Neovascular Glaucoma

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

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

Diabetic Retinopathy

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

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

Combination Product with Rinucumab

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

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

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

Combination Product with Nesvacumab

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

Late-Stage Antibody-based Clinical Programs

Praluent for LDL cholesterol reduction

Overview

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

Clinical Programs

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

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

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

- Ninety-three percent of patients treated with Praluent experienced at least a 50% reduction in their apheresis procedures ($p<0.0001$).
- Throughout the trial, patients treated with Praluent experienced significant reductions in their LDL cholesterol starting

at week 6 (55% greater reduction compared to placebo), and lasting until the trial ended, at week 18 (46% greater reduction compared to placebo) ($p<0.0001$).

- A similar proportion of patients experienced adverse events (AEs) in both the Praluent and placebo groups (76% in both groups). The most common AEs (occurring in at least 5% of the Praluent group) were fatigue (15% Praluent; 10% placebo), nasopharyngitis (10% Praluent; 10% placebo), diarrhea (10% Praluent; 0% placebo), myalgia (10% Praluent; 5% placebo), upper respiratory infection (7% Praluent; 19% placebo), headache (7% Praluent; 5% placebo), arthralgia (7% Praluent; 10% placebo), and back pain (5% Praluent; 10% placebo).

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

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

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

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

Overview

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

Rheumatoid Arthritis

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

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

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

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

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

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

Non-infectious Uveitis

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

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

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

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

Overview

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

Atopic Dermatitis

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

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

In 2015, the United Kingdom (UK) Medicines & Healthcare products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) Designation to Dupixent in the short-term treatment of adult patients with severe atopic dermatitis who have responded inadequately to all available topical prescription treatments and/or systemic ciclosporin, or who are intolerant of or ineligible for such treatments. A PIM Designation is an early indication that a medicinal product is a promising candidate for the Early Access to Medicines Scheme (EAMS), in the treatment,

diagnosis, or prevention of life-threatening or seriously debilitating conditions with unmet need. PIM Designation is the first step in a 2-step EAMS process that allows patients to be treated with Dupixent in advance of formal regulatory approval.

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

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

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

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

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

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

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

The secondary endpoint 52-week results were the following:

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

- 64% of patients who received 300 mg weekly with TCS, and 65% of patients who received 300 mg every two weeks with TCS achieved EASI-75, compared to 22% with placebo with TCS (p<0.0001).

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

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

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

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

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

Asthma

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

Nasal Polyps

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

Eosinophilic Esophagitis

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

REGN2222 (RSV-F Antibody) for RSV

Overview

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

Clinical Program

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

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

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

Overview

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

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

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Osteoarthritis

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

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

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

Chronic Low Back Pain

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

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

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

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

Research Programs

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

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

Collaboration Agreements

Collaborations with Sanofi

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

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

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

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable up-front payment to us. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with us through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between us and

Sanofi on a candidate-by-candidate basis. Sanofi will fund drug candidate development costs up front for the candidates for which it is the principal controlling party and we will reimburse half of the total development costs for all such candidates from our share of future profits to the extent they are sufficient for this purpose. In addition, we and Sanofi will share equally, on an ongoing basis, the development costs for the drug candidates for which we are the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. The parties will share equally in profits and losses in connection with the commercialization of collaboration products.

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

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

Collaborations with Bayer

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

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

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

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

Ang2 antibody outside the United States. In March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. Nesvacumab/aflibercept, a combination product candidate comprised of an antibody to Ang2 co-formulated with aflibercept, is being developed under the agreement. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to us and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. We are also entitled to receive an aggregate of $80.0 million in development milestone payments from Bayer. Bayer will share profits and losses from sales outside the United States equally with us, and is responsible for certain royalties payable to Sanofi on sales of the product outside of the United States. Within the United States, we have exclusive commercialization rights and will retain all of the profits from sales. Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as neither party or its respective affiliates or sublicensees is developing or commercializing an Ang2 antibody in the specified field outside of the United States and such discontinuation is acknowledged as permanent by both us and

Bayer.

Collaboration with Mitsubishi Tanabe Pharma

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

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

Collaboration with Teva

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

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

Collaboration with Intellia Therapeutics

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

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

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

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

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

Collaboration with Adicet Bio

In July 2016, we entered into a license and collaboration agreement with Adicet Bio, Inc., a privately held company, to develop next-generation engineered immune-cell therapeutics with fully human chimeric antigen receptors (CARs)

and T-cell receptors (TCRs) directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells. In connection with the execution of the agreement, we made a $25.0 million up-front payment to Adicet, and are obligated to provide Adicet with research funding over the course of a five-year research term.

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

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

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

General

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

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

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

Trap-based Clinical Program:

| | 2016 Events to Date | 2016-2017 Plans (next 12 months) |
|---|---|---|
| EYLEA | Bayer received regulatory approval for EYLEA for various indications and continued to pursue regulatory applications for marketing approval in additional countries<br>Initiated Phase 3 study for the treatment of NPDR in patients without DME<br>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<br>Regulatory agency decisions on applications outside the United States for various indications |

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| 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 |
| | | Submit for additional regulatory approvals outside the United States |
| | The DMC of the ODYSSEY OUTCOMES study completed the first interim analysis for futility and recommended the study continue with no changes | Regulatory agency and reimbursement authority decisions on applications outside the United States |
| | | Prespecified early-stopping interim analysis by DMC of ODYSSEY OUTCOMES trial |
| | Supplemental BLA for monthly dosing regimen accepted for review by the FDA | |
| | Regulatory application filed for monthly dosing regimen in the EU | FDA target action date of January 24, 2017 for monthly dosing regimen |
| | 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, Japan, and other jurisdictions outside the United States | Sanofi to implement corrective actions pursuant to the CRL issued by the FDA |
| | Presented 52-week top-line data from Phase 2 SARIL-NIU-SATURN study at American Academy of Ophthalmology conference | Submit for additional regulatory approvals outside the United States |
| | FDA issued CRL regarding the BLA | |
| | Initiated Phase 2 study in pJIA | |
| Dupixent (dupilumab; IL-4R Antibody) | Reported positive top-line results from Phase 3 LIBERTY AD SOLO 1 and SOLO 2 trials | Submit for EU, Japan, and other regulatory approvals in atopic dermatitis outside the United States |
| | Initiated Phase 3 LIBERTY AD CAFÉ study in atopic dermatitis | Initiate Phase 3 studies in pediatric patients in atopic dermatitis and asthma |
| | Reported positive results from Phase 3 LIBERTY AD CHRONOS study in atopic dermatitis | Initiate Phase 3 study in patients with nasal polyps |
| | FDA accepted for priority review the BLA for atopic dermatitis | Complete patient enrollment in Phase 2 EoE study |
| | LIBERTY AD SOLO 1 and SOLO 2 results presented at EADV conference and simultaneously published in the New England Journal of Medicine | |
| | Completed patient enrollment in pivotal Phase 3 LIBERTY ASTHMA QUEST study | |
| | FDA granted Breakthrough Therapy designation for the treatment of atopic dermatitis in pediatric patients | |

| | | |
|---|---|---|
| REGN2222 (RSV-F Antibody) | | Complete 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 or hip | Continue patient enrollment in Phase 3 long-term safety and efficacy study in osteoarthritis |
| | Initiated Phase 2b 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 | Initiate additional Phase 3 efficacy study in patients with osteoarthritis pain |
| | Phase 2b study in chronic low back pain put on clinical hold by FDA | Design pivotal Phase 3 study in chronic low back pain that excludes patients with advanced osteoarthritis |

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Antibody-based Clinical Programs (continued):

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

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furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

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

Results of Operations

Three Months Ended September 30, 2016 and 2015

Net Income

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

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

Revenues

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

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

Net Product Sales

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

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

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| (In millions) | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of June 30, 2016 | $ 11.6 | $ 28.1 | $ 1.1 | $40.8 |
| Provision related to current period sales | 22.2 | 39.5 | 10.5 | 72.2 |
| Credits/payments | (26.4) | (41.0) | (7.8) | (75.2) |
| Balance as of September 30, 2016 | $ 7.4 | $ 26.6 | $ 3.8 | $37.8 |
| | | | | |
| Balance as of June 30, 2015 | $ 5.5 | $ 39.5 | $ 0.5 | $45.5 |
| Provision related to current period sales | 15.8 | 33.3 | 2.6 | 51.7 |
| Credits/payments | (14.9) | (34.6) | (2.6) | (52.1) |
| Balance as of September 30, 2015 | $ 6.4 | $ 38.2 | $ 0.5 | $45.1 |

Sanofi Collaboration Revenue

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

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

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

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

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

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

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

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

Bayer Collaboration Revenue

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

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

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

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Regeneron's Net Profit from EYLEA Sales Outside the United States

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

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

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

As described above under "Collaboration Agreements - Collaborations with Bayer - Ang2 antibody outside the United States," in March 2016, we entered into an agreement with Bayer governing the joint development and commercialization outside the United States of nesvacumab, an antibody product candidate to Ang2, including in combination with aflibercept, for the treatment of ocular diseases or disorders. Nesvacumab/aflibercept, a combination product candidate comprised of an antibody to Ang2 co-formulated with aflibercept, is being developed under the agreement. In connection with the agreement, Bayer made a $50.0 million non-refundable up-front payment to us and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States. As of September 30, 2016, $47.8 million of the up-front and other payments was deferred and will be recognized ratably as revenue in future periods.

Other Revenue

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

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

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

Expenses

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

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

Research and Development Expenses

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

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

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

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

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

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

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

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

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

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

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

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Selling, General, and Administrative Expenses

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

Cost of Goods Sold

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

Cost of Collaboration and Contract Manufacturing

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

Income Taxes

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

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

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Nine Months Ended September 30, 2016 and 2015

Net Income

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

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

Revenues

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

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

Net Product Sales

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

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

| (In millions) | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2015 | $ 6.4 | $ 48.3 | $ 0.5 | $55.2 |
| Provision related to current period sales | 63.5 | 113.8 | 22.8 | 200.1 |
| Credits/payments | (62.5) | (135.5) | (19.5) | (217.5) |
| Balance as of September 30, 2016 | $ 7.4 | $ 26.6 | $ 3.8 | $37.8 |
| | | | | |
| Balance as of December 31, 2014 | $ 3.1 | $ 21.2 | $ 0.5 | $24.8 |
| Provision related to current period sales | 41.3 | 88.0 | 6.0 | 135.3 |
| Credits/payments | (38.0) | (71.0) | (6.0) | (115.0) |
| Balance as of September 30, 2015 | $ 6.4 | $ 38.2 | $ 0.5 | $45.1 |

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Sanofi Collaboration Revenue

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

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

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

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

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

by Sanofi, were $75.7 million and $4.0 million in the first nine months of 2016 and 2015, respectively.

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

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

Bayer Collaboration Revenue

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

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

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

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

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

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

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

Other Revenue

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

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

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

Expenses

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

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

Research and Development Expenses

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

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

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

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

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

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

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

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

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

Selling, General, and Administrative Expenses

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

Cost of Goods Sold

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

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Cost of Collaboration and Contract Manufacturing

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

Other Income and Expense

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

Income Taxes

In the first nine months of 2016 and 2015, we recorded income tax expense of $345.9 million and $516.7 million, respectively. The effective tax rate was 35.0% and 51.8% for the first nine months of 2016 and 2015, respectively.

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

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

Liquidity and Capital Resources

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

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

Cash Provided by Operating Activities

Net cash provided by operating activities was $1,095.5 million in the first nine months of 2016. Our net income of $642.4 million in the first nine months of 2016 included Non-cash Compensation Expense of $405.3 million and depreciation and amortization of $75.8 million. Deferred tax assets as of September 30, 2016 increased by $190.3 million, compared to December 31, 2015, primarily due to an increase in share-based compensation, the tax basis of intangible assets, and deferred revenue.

As of September 30, 2016, Sanofi, Bayer, and trade accounts receivable increased by $176.1 million, compared to December 31, 2015, primarily due to higher U.S. EYLEA sales. Inventories as of September 30, 2016 increased by $99.7 million, compared to December 31, 2015, primarily due to increased production of commercial supplies of EYLEA and Praluent. Deferred revenue increased by $282.2 million as of September 30, 2016, compared to December 31, 2015, primarily due to $250.0 million and $60.0 million of payments received in the first nine months of 2016 from Teva and Mitsubishi, respectively, in connection with the companies' respective fasinumab collaborations, and the $50.0 million up-front payment from Bayer in connection with the companies' Ang2 collaboration (as described above), partly offset by the amortization of these 2016 payments and past up-front payments from Sanofi. Accounts payable, accrued expenses, and other liabilities increased by $107.4 million as of September 30, 2016, compared to December 31, 2015, primarily due to higher tax-related liabilities, partly offset by lower royalties payable since our obligation to pay Genentech based on sales of EYLEA ended in May 2016.

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

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

Cash Used in Investing Activities

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

Cash Used in Financing Activities

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

Credit Facility

In March 2015, we entered into an agreement with a syndicate of lenders (the Credit Agreement) which provides for a $750.0 million senior unsecured five-year revolving credit facility (the Credit Facility). The Credit Agreement includes an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the

lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty. We had no borrowings outstanding under the Credit Facility as of September 30, 2016.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. We were in compliance with all covenants of the Credit Facility as of September 30, 2016.

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Capital Expenditures

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

Funding Requirements

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

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

Under our collaborations with Sanofi and Bayer, we and our collaborator share profits and losses in connection with commercialization of drug products. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collaboration agreements. Currently, we are required to pay royalties on sales of certain commercial products.

Under the provisions of the federal Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act of 2010, the Branded Prescription Drug Fee is imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. This fee is allocated to companies, including us, based on their market share of total branded prescription drug sales into these government programs.

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

We enter into research collaboration and licensing agreements that may require us to pay (i) amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant, and/or (ii) royalties calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted.

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

Future Impact of Recently Issued Accounting Standards

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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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 September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business, including those described in our Annual Report on Form 10-K for the year ended December 31, 2015 (filed February 11, 2016), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016 (filed May 5, 2016), our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016 (filed August 4, 2016), and those described below. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. For a description of risks relating to these and other legal proceedings we face, see Part II, Item 1A. "Risk Factors," including the discussion under the headings entitled "Risks Related to Intellectual Property and Market Exclusivity," "Regulatory and Litigation Risks," and "Risks Related to Our Common Stock."

Proceedings Relating to '287 Patent and '163 Patent

As previously reported, on September 25, 2013, we commenced patent infringement litigation against Kymab Ltd in the English High Court of Justice, Chancery Division, Patents Court, in London, asserting our European Patent No. 1,360,287 (the '287 Patent) and European Patent No. 2,264,163 (the '163 Patent), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse. A trial to adjudicate the claims of infringement and counterclaims of invalidity of the '287 Patent and the '163 Patent was held from November 16, 2015 through December 8, 2015. On February 1, 2016, the court issued a final judgment, finding that the asserted claims of the '287 and '163 Patents are novel, not obvious, and infringed by Kymab's genetically engineered mice. However, the court invalidated the '287 and '163 Patents on the ground of insufficiency. On April 27, 2016, the court granted permission for our appeal and Kymab's cross-appeal, and on May 18, 2016, Regeneron and Kymab filed their respective notices to appeal the court's decision on the '287 and '163 Patents. The hearing for the appeal and the cross-appeal is currently scheduled for October 2017.

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

Proceedings Relating to Praluent (alirocumab) Injection

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

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

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

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

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

Proceedings Relating to Patents Owned by Genentech and City of Hope

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

Proceedings Relating to Shareholder Derivative Claim

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

ITEM 1A. RISK FACTORS

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

Risks Related to Commercialization of EYLEA

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

EYLEA net sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the nine months ended September 30, 2016 and 2015, EYLEA net sales in the United States represented 68% and 64% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

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

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

- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of

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regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;

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

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

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

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

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

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

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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. 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.

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Risks Related to Commercialization of Praluent

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The commercial success of Praluent is subject to strong competition.

There is significant actual and potential future competition for Praluent. Amgen's PCSK9 program is currently the most advanced of the competitors, having already received regulatory approvals in jurisdictions including the U.S., the EU, and Japan for its PCSK9 inhibitor Repatha. Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries. Several other companies, including AstraZeneca PLC and Eli Lilly and Company, also have development programs for antibodies against PCSK9. Alnylam Pharmaceuticals, Inc, in collaboration with The Medicines Company, has a clinical program underway with an RNAi molecule against PCSK9. In addition, there are therapeutic products targeting PCSK9 operating through other mechanisms of action in development, including oral products and vaccines. Oral products that lower LDL-C, if

approved, may also be competitive with PCSK9 inhibitors, including Praluent. Certain late-stage inhibitors of cholesterylester transfer protein (CETP), such as Merck &Co., Inc's anacetrapib, lower LDL-C and may be launched with supporting data from outcomes trials prior to the completion of our own outcomes trial for Praluent. Other oral agents for lowering LDL-C that may potentially compete with Praluent include ETC-1002, which is being developed by Esperion Therapeutics, Inc.; and gemcabene, which is being developed by Gemphire Therapeutics Inc.

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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, and clinical trials evaluating our product candidates failed to meet the relevant endpoints. For example, in September 2016, we reported that in the Phase 2 study evaluating aflibercept co-formulated with rinucumab, an anti-platelet-derived growth factor receptor beta (anti-PDGFR-beta) antibody, in patients with wet AMD, the combination therapy did not demonstrate an improvement in best corrected visual acuity compared to intravitreal aflibercept injection monotherapy at 12 weeks. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval. For instance, based on the results of three Phase 3 studies, we submitted a supplemental BLA filing to the FDA seeking approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. In May 2012, the Arthritis Advisory Committee of the FDA voted to recommend against approval of ARCALYST for the prevention of gout flares in patients initiating uric acid-lowering drug therapy and, in July 2012, we received a Complete Response letter from the FDA requesting additional information, including clinical data, as well as additional CMC information related to a proposed new dosage form. We have discontinued development of ARCALYST for gout.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAP as a first-line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC

after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

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

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

Risks Related to Intellectual Property and Market Exclusivity

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. Patent applications filed outside the United States may be challenged by other parties, for example, by filing third-party observations that argue against patentability or an opposition. Such opposition proceedings are increasingly common in the EU and are costly to defend. For example, our European Patent No. 1,360,287 was, and our European Patent No. 2,264,163 is, the subject of opposition proceedings in the European Patent Office, as described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2015 and in Part II, Item 1. "Legal Proceedings" of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2016 and June 30, 2016, respectively, and this report (as applicable). We have pending patent applications in the United States Patent and Trademark Office, the European Patent Office, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend

patents from challenges by others from time to time in the future. Certain of our U.S. patents may also be challenged by parties who file a request for post-grant review or inter partes reexamination under the America Invents Act of 2011 or ex parte reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Manufacturing and Supply

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

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

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

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

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

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

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

We have large-scale manufacturing operations in Rensselaer, New York and are in the process of building a large-scale manufacturing facility in Limerick, Ireland. We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications

of our marketed products and new product candidates if they are approved for marketing. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could adversely affect our operating results.

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

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

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

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

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

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

We and our third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facility in Rensselaer, New York, including EYLEA, Praluent, ZALTRAP, and ARCALYST, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our late-stage product candidates or new indications for our marketed products. For example, on October 28, 2016, the FDA issued a complete response letter relating to the BLA for sarilumab, which referred to certain deficiencies identified during a routine cGMP inspection of the Sanofi

facility in Le Trait, France where sarilumab is filled and finished; satisfactory resolution of these deficiencies is required before the BLA can be approved. While Sanofi submitted a comprehensive corrective action plan to the FDA and is implementing the corrective actions specified in that plan, there is no guarantee that Sanofi will be able to resolve those deficiencies timely or at all. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

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Risks Related to Commercialization of Products

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

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

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

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

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

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

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

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

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

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

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early- and late-stage product candidates. For example, Pfizer (in collaboration with Eli Lilly) is developing an antibody product candidate against NGF. Genentech/Roche is marketing an antibody against IL-6R (Actemra® (tocilizumab)) for the treatment of rheumatoid arthritis that would compete with sarilumab, our IL-6R antibody, if it is approved. In addition, several other companies, including Johnson & Johnson (in collaboration with GlaxoSmithKline plc), Alder Biopharmaceuticals, Inc., Ablynx (in collaboration with AbbVie), and R-Pharm, have antibodies against IL-6 or

IL-6R in clinical development. A number of companies are developing antibodies that, if approved, may compete with Dupixent, our IL-4R antibody, if it is approved, including Roche (an antibody against IL-13), AstraZeneca (antibodies against IL-4R, IL-5R, and IL-13), Novartis (a combination antibody against IL-4 and IL-13), and Amgen (in collaboration with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). GlaxoSmithKline's Nucala® (mepolizumab) and Teva's Cinqair® (reslizumab), both of which are antibodies against IL-5, may also compete with Dupixent, if Dupixent is approved. For RSV, AstraZeneca commercializes an RSV-F protein antibody Synagis® (palivizumab), and other antibodies are in clinical development, including by AstraZeneca (in collaboration with AIMM Therapeutics).

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

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

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

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

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

for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

There is a risk that third-party payers, including Medicare and Medicaid in the United States, may not cover and/or reimburse our current and future products at levels required for us to successfully commercialize these products. Any limitation imposed by third-party payers on the use of our products if they are approved for marketing, or any action or decision by CMS or analogous foreign agencies or authorities which for any reason denies coverage or reimbursement for our products or provides coverage or reimbursement at levels that harm our products' competitiveness or leads to lower prices for those products, will have a material negative effect on our ability to sustain profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into

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account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

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

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the nine months ended September 30, 2016, we recorded 99% of our total gross product revenue from sales to three distributors, and a single distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation, accounted for 56% of our total gross product revenue in the same period. We expect this significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of EYLEA will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of EYLEA to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

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

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

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

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

Regulatory and Litigation Risks

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

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an

adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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If we market and sell approved products in a way that violates federal or state healthcare laws, we may be subject to civil or criminal penalties.

The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA's review of promotional activities includes healthcare provider-directed and direct-to-consumer advertising as well as sales representatives' communications. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

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

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

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

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

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

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

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

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

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

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

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

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;

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

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing

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drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

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

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

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

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

We may incur additional tax liabilities related to our operations.

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

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

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. For example, as part of our human genetics initiative, our wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with research institutions, including the Geisinger Health System, which are subject to such regulations. Regeneron is not currently classified as a covered entity or business associate under

HIPAA and thus is not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

respect to those antibodies that Sanofi elects to co-develop with us under our Antibody Collaboration (such as Praluent, sarilumab, and Dupixent) or for which Sanofi is the principal controlling party under our IO Collaboration, we rely on Sanofi to lead much of the clinical development efforts and assist with obtaining and maintaining regulatory approval. Following regulatory approval, we also rely on Sanofi to lead (i) the commercialization efforts to support all of the antibody products that are co-developed by Sanofi and us under our Antibody Collaboration and (ii) the commercialization efforts outside the Unites States to support all products that are co-developed by Sanofi and us under our IO Collaboration (as well as the commercialization efforts in the United States to support all products for which Sanofi is the principal controlling party under our IO Collaboration).

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

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

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

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

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

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

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

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Risk Related to Employees

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

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

Information Technology Risks

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

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

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

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders, and our largest shareholder, Sanofi, has been maintaining its percentage ownership of our Common Stock and has publicly disclosed that it may opportunistically increase its percentage ownership of our Common Stock. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

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Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2016, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 51.3% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2016. As of September 30, 2016, Sanofi beneficially owned 23,418,396 shares of our Common Stock, representing approximately 22.6% of the shares of Common Stock then outstanding. Under our January 2014 amended and restated investor agreement with Sanofi, Sanofi has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten offering with respect to shares of our Common Stock held by Sanofi from time to time; however, shares of our Common Stock held by Sanofi from time to time may not be sold until the later of (i) December 20, 2020 and (ii) the expiration of our Antibody Discovery Agreement with Sanofi relating to our Antibody Collaboration (as amended) if the agreement is extended beyond December 20, 2020. These restrictions on dispositions are subject to earlier termination upon the occurrence of certain events, such as the consummation of a change-of-control transaction involving us or a dissolution or liquidation of our company. In February 2013, we received from Sanofi a notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 that it intends to acquire additional Common Stock through open market purchases and direct purchases from shareholders. In December 2015, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase (subject to market conditions, including the price and availability of shares of our Common Stock, and legal and regulatory requirements) additional shares of our Common Stock to maintain and opportunistically increase its beneficial ownership on a percentage basis up to the maximum allowed under the "standstill" provisions of our amended and restated investor agreement with Sanofi, or 30% of our Class A Stock and Common Stock (taken together). If Sanofi, our other significant shareholders, or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including Sanofi, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

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

- our current executive officers and directors beneficially owned 10.3% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2016, and 21.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2016; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 51.3% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2016. In addition, these five shareholders plus our Chief Executive Officer held approximately 56.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30,

2016.

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

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

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

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

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

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

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

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

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our company and an "interested shareholder," a plan of merger or consolidation of our company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "Our existing shareholders may be able to exert significant influence over matters requiring

shareholder approval and over our management."

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

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

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

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

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

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

Issuer Purchases of Equity Securities

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

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

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ITEM 6. EXHIBITS

(a) Exhibits

| Exhibit Number | Description |
|---|---|
| 10.1 * | Collaboration Agreement, dated as of September 17, 2016, by and between Teva Pharmaceuticals International GmbH and Regeneron Ireland. |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 31.2 | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 32 | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350. |
| 101 | Interactive Data File |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF | XBRL Taxonomy Extension Definition Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase |

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

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REGENERON
PHARMACEUTICALS, INC.

Date: November 4, 2016 By: /s/ Robert E. Landry

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