REGENERON PHARMACEUTICALS INC
Form 10-Q
November 04, 2015
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q

(Mark One)

(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

OR

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

Commission File Number 0-19034

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

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

(914) 847-7000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

| | | |
|---|---|---|
| Yes | X | No |

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

| | | |
|---|---|---|
| Yes | X | No |

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

| | | |
|---|---|---|
| Yes | No | X |

Number of shares outstanding of each of the registrant's classes of common stock as of October 16, 2015:

| Class of Common Stock | Number of Shares |
|---|---|
| Class A Stock, $.001 par value | 1,913,776 |
| Common Stock, $.001 par value | 102,151,256 |

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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, 2015 | December 31, 2014 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $654,587 | $648,719 |
| Marketable securities | 241,055 | 251,761 |
| Accounts receivable - trade, net | 1,088,207 | 739,379 |
| Accounts receivable from Sanofi | 199,117 | 111,510 |
| Accounts receivable from Bayer HealthCare | 151,991 | 125,483 |
| Inventories | 190,668 | 128,861 |
| Deferred tax assets | 60,521 | 46,179 |
| Prepaid expenses and other current assets | 89,494 | 79,046 |
| Total current assets | 2,675,640 | 2,130,938 |
| Marketable securities | 681,326 | 460,154 |
| Property, plant, and equipment, at cost, net of accumulated depreciation and amortization | 1,475,123 | 974,309 |
| Deferred tax assets | 346,243 | 269,237 |
| Other assets | 4,583 | 3,034 |
| Total assets | $5,182,915 | $3,837,672 |
| LIABILITIES and STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $577,428 | $483,489 |
| Deferred revenue from Sanofi, current portion | 100,908 | 15,927 |
| Deferred revenue - other, current portion | 54,148 | 58,098 |
| Other current liabilities | 2,506 | 97,146 |
| Total current liabilities | 734,990 | 654,660 |
| Deferred revenue from Sanofi | 599,339 | 62,819 |
| Deferred revenue - other | 78,942 | 72,430 |
| Facility lease obligations | 364,144 | 310,938 |
| Convertible senior notes | 30,723 | 146,773 |
| Other long-term liabilities | 77,910 | 39,801 |
| Total liabilities | 1,886,048 | 1,287,421 |
| 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 - 1,914,776 in 2015 and 1,973,368 in 2014 | 2 | 2 |
| Common Stock, $.001 par value; 320,000,000 shares authorized; shares issued - 105,572,737 in 2015 and 102,475,154 in 2014 | 106 | 102 |

| | | |
|---|---|---|
| Additional paid-in capital | 2,880,109 | 2,450,782 |
| Retained earnings | 697,706 | 216,644 |
| Accumulated other comprehensive income | 7,721 | 52,251 |
| Treasury stock, at cost; 3,437,000 shares in 2015 and 2,017,732 in 2014 | (288,777) | (169,530) |
| Total stockholders' equity | 3,296,867 | 2,550,251 |
| Total liabilities and stockholders' equity | $5,182,915 | $3,837,672 |

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, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Statements of Operations | | | | |
| Revenues: | | | | |
| Net product sales | $737,562 | $448,844 | $1,939,954 | $1,229,244 |
| Sanofi collaboration revenue | 224,735 | 132,925 | 593,201 | 406,028 |
| Bayer HealthCare collaboration revenue | 157,596 | 135,853 | 415,679 | 358,460 |
| Technology licensing and other revenue | 17,529 | 8,166 | 56,817 | 23,496 |
| | 1,137,422 | 725,788 | 3,005,651 | 2,017,228 |
| Expenses: | | | | |
| Research and development | 425,924 | 337,728 | 1,159,367 | 919,608 |
| Selling, general, and administrative | 209,993 | 144,003 | 543,572 | 343,960 |
| Cost of goods sold | 67,199 | 33,655 | 170,624 | 91,073 |
| Cost of collaboration and contract manufacturing | 41,884 | 21,938 | 111,254 | 54,471 |
| | 745,000 | 537,324 | 1,984,817 | 1,409,112 |
| Income from operations | 392,422 | 188,464 | 1,020,834 | 608,116 |
| Other income (expense): | | | | |
| Investment and other income | 2,603 | 2,591 | 4,533 | 5,205 |
| Interest expense | (1,715) | (9,232) | (10,632) | (31,022) |
| Loss on extinguishment of debt | (21) | — | (16,927) | (10,787) |
| | 867 | (6,641) | (23,026) | (36,604) |
| Income before income taxes | 393,289 | 181,823 | 997,808 | 571,512 |
| Income tax expense | (182,891) | (98,448) | (516,746) | (323,481) |
| Net income | $210,398 | $83,375 | $481,062 | $248,031 |
| Net income per share - basic | $2.04 | $0.83 | $4.68 | $2.47 |
| Net income per share - diluted | $1.82 | $0.73 | $4.18 | $2.19 |
| Weighted average shares outstanding - basic | 103,348 | 100,796 | 102,825 | 100,325 |
| Weighted average shares outstanding - diluted | 115,944 | 117,423 | 115,144 | 113,203 |
| Statements of Comprehensive Income | | | | |
| Net income | $210,398 | $83,375 | $481,062 | $248,031 |
| Other comprehensive (loss) income: | | | | |
| Unrealized (loss) gain on marketable securities, net of tax | (11,432) | 22,632 | (44,530) | 28,083 |
| Comprehensive income | $198,966 | $106,007 | $436,532 | $276,114 |

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, | |
|---|---|---|
| | 2015 | 2014 |
| Cash flows from operating activities: | | |
| Net income | $481,062 | $248,031 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 51,999 | 38,551 |
| Non-cash compensation expense | 300,657 | 208,732 |
| Loss on extinguishment of debt | 16,927 | 10,787 |
| Other non-cash charges and expenses, net | 33,197 | 28,473 |
| Deferred taxes | (65,975) | (34,161) |
| Changes in assets and liabilities: | | |
| (Increase) decrease in Sanofi, Bayer HealthCare, and trade accounts receivable | (462,943) | 53,642 |
| Increase in inventories | (81,459) | (50,917) |
| Increase in prepaid expenses and other assets | (13,223) | (28,850) |
| Increase in deferred revenue | 624,063 | 3,466 |
| Increase in accounts payable, accrued expenses, and other liabilities | 164,652 | 76,506 |
| Total adjustments | 567,895 | 306,229 |
| Net cash provided by operating activities | 1,048,957 | 554,260 |
| | | |
| Cash flows from investing activities: | | |
| Purchases of marketable securities | (550,142) | (478,436) |
| Sales or maturities of marketable securities | 265,995 | 216,478 |
| Capital expenditures | (500,154) | (215,464) |
| Net cash used in investing activities | (784,301) | (477,422) |
| | | |
| Cash flows from financing activities: | | |
| Proceeds (payments) in connection with facility and capital lease obligations | 26,405 | (810) |
| Repayments of convertible senior notes | (146,007) | (61,125) |
| Payments in connection with reduction of outstanding warrants | (523,487) | (143,041) |
| Proceeds from issuance of Common Stock | 150,423 | 80,804 |
| Payments in connection with Common Stock tendered for employee tax obligations | (71,673) | (175,866) |
| Excess tax benefit from stock-based compensation | 305,551 | 334,146 |
| Net cash (used in) provided by financing activities | (258,788) | 34,108 |
| | | |
| Net increase in cash and cash equivalents | 5,868 | 110,946 |
| | | |
| Cash and cash equivalents at beginning of period | 648,719 | 535,608 |
| | | |
| Cash and cash equivalents at end of period | $654,587 | $646,554 |

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

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

1. Interim Financial Statements

The interim Condensed Consolidated Financial Statements of Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2014 Condensed Consolidated Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014.

The previously issued (i) Consolidated Balance Sheet as of December 31, 2014 contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and (ii) Condensed Consolidated Statement of Operations and Comprehensive Income for the three and nine months ended September 30, 2014 and Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2014 contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, have each been revised in this Quarterly Report on Form 10-Q to reflect a correction in the Company's accounting for certain stock option awards. See Note 4.

In addition, the previously issued Consolidated Balance Sheet as of December 31, 2014 in this Quarterly Report on Form 10-Q was previously revised to reflect a correction related to the accounting for costs incurred in connection with commercial bulk drug product manufactured by the Company, but not billed, under the Company's collaboration agreements with Sanofi and Bayer HealthCare, and the related tax impacts. The correcting adjustments resulted in a reduction to both accounts receivable and deferred revenue by $41.0 million, and reduced both income tax assets, net and additional paid-in capital by $14.2 million. The previously issued Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2014 was also revised in this Quarterly Report on Form 10-Q to reflect a $9.4 million increase in cash flows from operating activities and a corresponding reduction in cash flows from financing activities related to the tax impact of these adjustments. These adjustments had no impact on the Company's previously issued Consolidated Statements of Operations and Comprehensive Income in any reporting period. The Company determined that the error is not material to any previously-issued financial statements.

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 $734.4 million and $445.0 million for the three months ended September 30, 2015 and 2014, respectively, and $1,930.0 million and $1,218.8 million for the nine months ended September 30, 2015 and 2014, respectively. In addition, ARCALYST® net product sales totaled $3.2 million and $3.8 million for the three months ended September 30, 2015 and 2014, respectively, and $9.9 million and $10.4 million for the nine months ended September 30, 2015 and 2014, respectively.

The Company recorded 65% and 72% for the three months ended September 30, 2015 and 2014, respectively, and 67% and 75% for the nine months ended September 30, 2015 and 2014, respectively, of its total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

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

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, distribution-related fees, and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for these sales-related deductions during the nine months ended September 30, 2015 and 2014.

| | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2014 | $3,083 | $21,166 | $532 | $24,781 |
| Provision related to current period sales | 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 |
| | | | | |
| Balance as of December 31, 2013 | $4,400 | $19,663 | $538 | $24,601 |
| Provision related to current period sales | 23,265 | 53,689 | 1,202 | 78,156 |
| Credits/payments | (23,873) | (54,878) | (1,211) | (79,962) |
| Balance as of September 30, 2014 | $3,792 | $18,474 | $529 | $22,795 |

Under the provisions of the Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education Reconciliation Act of 2010, a non-tax deductible annual fee (the "Branded Prescription Drug Fee") is imposed on pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. In July 2014, the Internal Revenue Service ("IRS") issued final regulations that provide guidance on the Branded Prescription Drug Fee. The final regulations differ in some respects from the temporary regulations previously issued by the IRS in 2011, including that a company is liable for the fee based on its branded prescription drug sales in the current year, instead of the liability only being applicable upon the first qualifying branded prescription drug sale of the following fee year under the temporary regulations. As a result of the issuance of these final IRS regulations, the Company began recording an estimate of the fee in the same period in which its qualifying branded prescription drug sales occur. Therefore, in the third quarter of 2014, an incremental charge was recorded to (i) recognize a liability for the estimated fee payable based on 2014 sales through the first nine months of 2014, and (ii) expense the remaining prepaid asset recorded under the previous accounting for the estimated fee payable based on 2013 sales. The impact of the incremental charge in the third quarter of 2014 was $40.6 million, which was included in selling, general, and administrative expenses.

3. Collaboration Agreements

a. Sanofi

Sanofi collaboration revenue, as detailed below, consisted primarily of reimbursement for research and development and commercialization expenses that the Company incurred, partly offset by sharing of losses in connection with commercialization of antibodies, under the companies' Discovery and Preclinical Development Agreement ("Antibody Discovery Agreement") and License and Collaboration Agreement (each as amended), collectively referred to as the "Antibody Collaboration". In addition, 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").

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

| | Three Months Ended September 30, | |
|---|---|---|
| Sanofi Collaboration Revenue | 2015 | 2014 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | $205,114 | $140,497 |
| Reimbursement of Regeneron commercialization-related expenses | 53,341 | 1,688 |
| Regeneron's share of losses in connection with commercialization of antibodies | (74,865) | (12,830) |
| Other | 2,561 | 2,561 |
| Total Antibody | 186,151 | 131,916 |
| Immuno-oncology: | | |
| Reimbursement of Regeneron research and development expenses | 18,584 | — |
| Other | 20,000 | — |
| Total Immuno-oncology | 38,584 | — |
| ZALTRAP®: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | — | (1,008) |
| Reimbursement of Regeneron research and development expenses | — | 1,261 |
| Other | — | 756 |
| Total ZALTRAP | — | 1,009 |
| | $224,735 | $132,925 |

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

| Sanofi Collaboration Revenue | Nine Months Ended September 30, 2015 | 2014 |
|---|---|---|
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | $585,450 | $405,212 |
| Reimbursement of Regeneron commercialization-related expenses | 89,145 | 7,062 |
| Regeneron's share of losses in connection with commercialization of antibodies | (143,583) | (17,125) |
| Other | 7,683 | 7,683 |
| Total Antibody | 538,695 | 402,832 |
| Immuno-oncology: | | |
| Reimbursement of Regeneron research and development expenses | 18,584 | — |
| Other | 20,000 | — |
| Total Immuno-oncology | 38,584 | — |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | — | (4,912) |
| Reimbursement of Regeneron research and development expenses | 686 | 3,691 |
| Other | 15,236 | 4,417 |
| Total ZALTRAP | 15,922 | 3,196 |
| | $593,201 | $406,028 |

Antibodies

Under the Company's November 2007 Antibody Collaboration with Sanofi, as amended, agreed upon worldwide research and development expenses incurred by both companies during the term of the agreement are funded by Sanofi, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by Sanofi and 20% by Regeneron. During the three months ended September 30, 2015 and 2014, the Company recognized as additional research and development expense $25.1 million and $28.4 million, respectively, and during the nine months ended September 30, 2015 and 2014, the Company recognized as additional research and development expense $72.6 million and $81.3 million, respectively, of antibody development expenses that the Company was obligated to reimburse to Sanofi related to Praluent® and sarilumab. In July 2014, in connection with the Company’s Antibody Collaboration with Sanofi, the Company purchased a U.S. Food and Drug Administration ("FDA") priority review voucher from a third party for $67.5 million. The Company and Sanofi equally shared the priority review voucher's purchase price, and the Company's share of the cost, or $33.8 million, was recorded as a research and development expense during the third quarter of 2014. The Company subsequently transferred the voucher to Sanofi, which used the priority review voucher in connection with the Biologics License Application submission to the FDA for Praluent.

Effective in the second and fourth quarters of 2014, the Company and Sanofi began sharing pre-launch commercialization expenses related to Praluent and sarilumab, respectively, in accordance with the companies’ License and Collaboration Agreement. In July 2015, the FDA approved Praluent for the treatment of adults with heterozygous

familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein ("LDL") cholesterol. In the third quarter of 2015, the Company also recorded its share of the Antibody Collaboration's losses in connection with commercialization of Praluent within Sanofi collaboration revenue.

In May 2013, the Company acquired from Sanofi full exclusive rights to antibodies targeting the platelet derived growth factor (PDGF) family of receptors and ligands in ophthalmology. With respect to PDGF antibodies, the Company made two $5.0 million development milestone payments to Sanofi in the first quarter of 2014 and a $10.0 million development milestone payment to

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Sanofi in the second quarter of 2015, each of which was recorded as research and development expense. The Company is also obligated to pay up to $20.0 million in additional potential development milestones as well as royalties on any future sales of PDGF antibodies.

In July 2015, in connection with the Company's new immuno-oncology collaboration with Sanofi, as described below, the Company's Antibody Discovery Agreement and License and Collaboration Agreement with Sanofi were each amended. In connection with these amendments, Sanofi's funding of the Company's antibody discovery activities under the existing Antibody Collaboration have been reduced from up to $160.0 million to up to $145.0 million in 2015, and from up to $160.0 million to up to $130.0 million in both 2016 and 2017, or an aggregate reduction of $75.0 million over this three-year period. In addition, the Company's discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will be funded by Sanofi under the terms of the companies' new immuno-oncology collaboration.

Immuno-Oncology

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 upfront payment to the Company. Pursuant to the IO Discovery Agreement, the Company 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 the Company for up to $825.0 million ("IO Discovery Funding") of these costs, subject to certain annual limits, which consists of (i) $750.0 million in new funding and (ii) $75.0 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery Agreement, as described above. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, the Company will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of Investigational New Drug ("IND") Applications, and clinical development through proof-of-concept. The Company 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 Regeneron's share of future profits, if any, from commercialized products to the extent they are sufficient for this purpose. However, the Company is not required to apply more than 10% of its share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. 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 (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, the Company will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable upfront payment to the Company. If Sanofi exercises its option to license rights to a product candidate thereunder, it will co-develop the drug candidate with the Company through product approval. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between the Company 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 the Company will reimburse half of the total development costs for all such candidates from its share of future profits to the extent they are sufficient for this purpose, subject to the same 10% reimbursement limitation described above. In addition, Sanofi and the Company

will share equally, on an ongoing basis, the development costs for the drug candidates for which the Company is 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. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop the Company's antibody product candidate targeting the receptor known as Programmed Cell Death protein 1, or PD-1 ("REGN2810"). The parties will

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

share equally, on an ongoing basis, development expenses for REGN2810 up to a total of $650.0 million. The Company will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. The Company will be entitled to a milestone payment of $375.0 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed $2.0 billion in any consecutive twelve-month period.

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, Sanofi or the Company may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

At the inception of the IO Collaboration, the Company's significant deliverables consisted of (i) 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 Sanofi 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 $640.0 million in aggregate upfront payments was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

ZALTRAP

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

In February 2015, the Company and Sanofi entered into an amended and restated ZALTRAP agreement ("Amended ZALTRAP Agreement"), with an effective date of July 1, 2014. Under the terms of the Amended ZALTRAP Agreement, Sanofi 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, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. The Company will also be paid for all quantities of ZALTRAP manufactured by it, pursuant to a supply agreement, through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities, or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement. Unless terminated earlier in accordance with its provisions, the Amended ZALTRAP Agreement will continue to be in effect until such time as neither Sanofi nor its affiliates or sublicensees is developing or commercializing ZALTRAP.

As a result of entering into the Amended ZALTRAP Agreement, in the first quarter of 2015, the Company recognized $14.9 million of 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 and nine months ended September 30, 2015, the Company recorded $9.0 million and $32.0 million, respectively, in technology licensing and other revenue, primarily related to (i) revenues earned from Sanofi based on a percentage of net sales of ZALTRAP and (ii) revenues earned from Sanofi for manufacturing ZALTRAP commercial supplies.

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b. Bayer HealthCare

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

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

| | Three Months Ended September 30, | |
|---|---|---|
| Bayer HealthCare Collaboration Revenue | 2015 | 2014 |
| EYLEA: | | |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $130,510 | $85,351 |
| Sales milestones | — | 30,000 |
| Cost-sharing of Regeneron EYLEA development expenses | 1,827 | 4,394 |
| Other | 21,155 | 12,745 |
| Total EYLEA | 153,492 | 132,490 |
| PDGFR-beta antibody: | | |
| Cost-sharing of REGN2176-3 development expenses | 1,508 | 518 |
| Other | 2,596 | 2,845 |
| Total PDGFR-beta | 4,104 | 3,363 |
| | $157,596 | $135,853 |

| | Nine Months Ended September 30, | |
|---|---|---|
| Bayer HealthCare Collaboration Revenue | 2015 | 2014 |
| EYLEA: | | |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $326,567 | $213,291 |
| Sales milestones | 15,000 | 75,000 |
| Cost-sharing of Regeneron EYLEA development expenses | 6,948 | 26,235 |
| Other | 50,685 | 34,490 |
| Total EYLEA | 399,200 | 349,016 |
| PDGFR-beta antibody: | | |
| Cost-sharing of REGN2176-3 development expenses | 8,688 | 1,657 |
| Other | 7,791 | 7,787 |
| Total PDGFR-beta | 16,479 | 9,444 |
| | $415,679 | $358,460 |

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EYLEA outside the United States

In the first quarter of 2015, the Company earned a $15.0 million sales milestone from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. During the nine months ended September 30, 2014, the Company earned five $15.0 million sales milestones (two of which were recorded in the third quarter of 2014) from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million, $600 million, $700 million, $800 million, and $900 million, respectively, over a twelve-month period.

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

PDGFR-beta antibody outside the United States

In January 2014, the Company entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to the Company in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. The $25.5 million upfront payment was initially recorded as deferred revenue, and will be recognized as revenue over the related performance period. Bayer HealthCare is also obligated to reimburse the Company for 50% of development milestone payments to Sanofi related to the Company's acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013, as described above. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to the Company in the first quarter of 2014 (both of which, for the purpose of revenue recognition, were not considered substantive) and a $5.0 million development milestone payment to the Company in the second quarter of 2015 (which was recognized as a substantive milestone).

c. Mitsubishi Tanabe Pharma

In September 2015, the Company and Mitsubishi Tanabe Pharma Corporation ("MTPC") entered into a collaboration agreement (the "MTPC Collaboration Agreement") providing MTPC with development and commercial rights to fasinumab, the Company's nerve growth factor antibody in late-stage clinical development, in Japan, South Korea, Taiwan, Indonesia, Thailand, the Philippines, Malaysia, Singapore, Vietnam, Myanmar, and Sri Lanka (the "MTPC Territories"). In connection with the MTPC Collaboration Agreement, MTPC made a $10.0 million non-refundable upfront payment, and the Company is entitled to receive up to an aggregate of $65.0 million in development milestones achieved by the Company and $150.0 million in other contingent payments, primarily related to development milestones achieved by MTPC.

Under the MTPC Collaboration Agreement, the Company is obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, the Company will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and is 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. Unless terminated earlier

in accordance with its provisions, the MTPC Collaboration Agreement will continue to be in effect until such time as MTPC has ceased developing or commercializing fasinumab in the MTPC Territories.

At the inception of the MTPC Collaboration Agreement, the Company's significant deliverables consisted of (i) exclusive rights to develop and commercialize fasinumab in the MTPC Territories, and (ii) manufacturing clinical and commercial supplies. The Company concluded that the license did not have standalone value, as such right was not sold separately by the Company, nor could MTPC receive any benefit from the license without the manufacturing services to be rendered by the Company. Therefore, the deliverables were considered a single unit of accounting. Consequently, the $10.0 million upfront payment was initially recorded as deferred revenue, and will be recognized ratably as revenue over the related performance period.

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4. Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's applicable Long-Term Incentive Plan based on the grant-date fair value of those awards. The Company recognized stock-based compensation expense of $102.6 million and $68.1 million for the three months ended September 30, 2015 and 2014, respectively, and $300.7 million and $208.7 million for the nine months ended September 30, 2015 and 2014, respectively.

Revisions of Previously-Issued Financial Statements

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

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

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

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

| | Nine Months Ended September 30, 2014 | | |
|---|---|---|---|
| | As Previously Reported | Adjustments | As Revised |
| Consolidated Statement of Cash Flows Data: | | | |
| Cash flows from operating activities | | | |
| Net income | $237,898 | $10,133 | $248,031 |
| Non-cash compensation expense | 225,784 | (17,052) | 208,732 |
| Deferred taxes | (50,466) | 6,919 | (43,547) |

The table below presents the impact of these revisions, including the related tax effects, on previously filed year-end Consolidated Statements of Operations for the three months and year ended December 31, 2014.

| | Three Months Ended December 31, 2014 | | | Year Ended December 31, 2014 | | |
|---|---|---|---|---|---|---|
| | As Previously Reported | Adjustments | As Revised | As Previously Reported | Adjustments | As Revised |
| Consolidated Statement of Operations Data: | | | | | | |
| Selling, general, and administrative | $143,743 | $31,564 | $175,307 | $504,755 | $14,512 | $519,267 |
| Total operating expenses | 554,962 | 31,564 | 586,526 | 1,981,126 | 14,512 | 1,995,638 |
| Income from operations | 247,367 | (31,564) | 215,803 | 838,431 | (14,512) | 823,919 |
| Income before income taxes | 221,287 | (31,564) | 189,723 | 775,747 | (14,512) | 761,235 |
| Income tax expense | 111,111 | (11,483) | 99,628 | 427,673 | (4,564) | 423,109 |
| Net income | 110,176 | (20,081) | 90,095 | 348,074 | (9,948) | 338,126 |
| Net income per share - basic | $1.09 | $(0.20) | $0.89 | $3.46 | $(0.10) | $3.36 |
| Net income per share - diluted | $0.96 | $(0.18) | $0.78 | $3.07 | $(0.09) | $2.98 |

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5. Net Income Per Share

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

| | Three Months Ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Net income - basic | $210,398 | $83,375 |
| Effective of dilutive securities: | | |
| Convertible senior notes - interest expense related to contractual coupon interest rate and amortization of discount and note issuance costs | 145 | 2,803 |
| Net income - diluted | $210,543 | $86,178 |
| | | |
| (Shares in thousands) | | |
| Weighted average shares - basic | 103,348 | 100,796 |
| Effect of dilutive securities: | | |
| Stock options | 9,632 | 9,377 |
| Restricted stock | 481 | 430 |
| Convertible senior notes | 308 | 4,033 |
| Warrants | 2,175 | 2,787 |
| Dilutive potential shares | 12,596 | 16,627 |
| Weighted average shares - diluted | 115,944 | 117,423 |
| | | |
| Net income per share - basic | $2.04 | $0.83 |
| Net income per share - diluted | $1.82 | $0.73 |

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| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Net income - basic and diluted | $481,062 | $248,031 |
| | | |
| (Shares in thousands) | | |
| Weighted average shares - basic | 102,825 | 100,325 |
| Effect of dilutive securities: | | |
| Stock options | 9,449 | 9,515 |
| Restricted stock | 475 | 413 |
| Warrants | 2,395 | 2,950 |
| Dilutive potential shares | 12,319 | 12,878 |
| Weighted average shares - diluted | 115,144 | 113,203 |
| | | |
| Net income per share - basic | $4.68 | $2.47 |
| Net income per share - diluted | $4.18 | $2.19 |

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) | 2015 | 2014 |
| Stock options | 594 | 1,277 |

| | Nine Months Ended September 30, | |
|---|---|---|
| (Shares in thousands) | 2015 | 2014 |
| Stock options | 3,388 | 3,741 |
| Convertible senior notes | 1,253 | 4,483 |

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6. Marketable Securities

Marketable securities as of September 30, 2015 and December 31, 2014 consist of both debt securities issued by investment grade institutions as well as equity securities. The Company also held restricted marketable securities as of December 31, 2014, consisting of the Company's investment in Avalanche Biotechnologies, Inc. common shares, which were subject to customary transfer restrictions until January 2015 under a lock-up agreement with the underwriters of Avalanche's initial public offering.

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

| As of September 30, 2015 | Amortized Cost Basis | Unrealized Gains | Losses | Fair Value |
|---|---|---|---|---|
| Unrestricted | | | | |
| Corporate bonds | $812,137 | $805 | $(988) | $811,954 |
| U.S. government and government agency obligations | 54,963 | 155 | (3) | 55,115 |
| Municipal bonds | 27,741 | 27 | (3) | 27,765 |
| Equity securities | 17,005 | 10,635 | (93) | 27,547 |
| | $911,846 | $11,622 | $(1,087) | $922,381 |
| | | | | |
| As of December 31, 2014 | | | | |
| Unrestricted | | | | |
| Corporate bonds | $548,832 | $136 | $(1,462) | $547,506 |
| U.S. government and government agency obligations | 28,596 | 3 | (46) | 28,553 |
| Municipal bonds | 37,044 | 37 | (43) | 37,038 |
| Equity securities | 2,005 | 5,374 | — | 7,379 |
| | 616,477 | 5,550 | (1,551) | 620,476 |
| Restricted | | | | |
| Equity securities | 15,000 | 76,439 | — | 91,439 |
| | $631,477 | $81,989 | $(1,551) | $711,915 |

The Company classifies its debt security investments based on their contractual maturity dates. The debt securities listed as of September 30, 2015 mature at various dates through August 2020. The fair values of debt security investments by contractual maturity consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Maturities within one year | $241,055 | $251,761 |
| Maturities after one year through five years | 653,779 | 360,208 |
| Maturities after five years through ten years | — | 1,128 |
| | $894,834 | $613,097 |

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The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position.

| | Less than 12 Months | | 12 Months or Greater | | Total | |
|---|---|---|---|---|---|---|
| As of September 30, 2015 | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss |
| Corporate bonds | $373,513 | $(960) | $27,779 | $(28) | $401,292 | $(988) |
| U.S. government and government agency obligations | 2,809 | (2) | 2,504 | (1) | 5,313 | (3) |
| Municipal bonds | 4,658 | (3) | — | — | 4,658 | (3) |
| Equity securities | 14,907 | (93) | — | — | 14,907 | (93) |
| | $395,887 | $(1,058) | $30,283 | $(29) | $426,170 | $(1,087) |
| As of December 31, 2014 | | | | | | |
| Corporate bonds | $390,613 | $(1,462) | — | — | $390,613 | $(1,462) |
| U.S. government and government agency obligations | 25,549 | (46) | — | — | 25,549 | (46) |
| Municipal bonds | 10,779 | (43) | — | — | 10,779 | (43) |
| | $426,941 | $(1,551) | — | — | $426,941 | $(1,551) |

For the three and nine months ended September 30, 2015 and 2014, total realized gains and losses on sales of marketable securities were not material.

Changes in the Company's accumulated other comprehensive income (loss) for the three and nine months ended September 30, 2015 and 2014 related to unrealized gains and losses on available-for-sale marketable securities. For the three and nine months ended September 30, 2015 and 2014, amounts reclassified from accumulated other comprehensive income (loss) into investment income in the Company's Statements of Operations were related to realized gains and losses on sales of marketable securities.

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7. Fair Value Measurements

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

| As of September 30, 2015 | Fair Value | Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---|---|---|---|
| Available-for-sale marketable securities: | | | |
| Unrestricted | | | |
| Corporate bonds | $811,954 | — | $811,954 |
| U.S. government and government agency obligations | 55,115 | — | 55,115 |
| Municipal bonds | 27,765 | — | 27,765 |
| Equity securities | 27,547 | $27,547 | — |
| | $922,381 | $27,547 | $894,834 |
| As of December 31, 2014 | | | |
| Available-for-sale marketable securities: | | | |
| Unrestricted | | | |
| Corporate bonds | $547,506 | — | $547,506 |
| U.S. government and government agency obligations | 28,553 | — | 28,553 |
| Municipal bonds | 37,038 | — | 37,038 |
| Equity securities | 7,379 | $7,379 | — |
| | 620,476 | 7,379 | 613,097 |
| Restricted | | | |
| Equity securities | 91,439 | — | 91,439 |
| | $711,915 | $7,379 | $704,536 |

Marketable securities included in Level 2 are valued using quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable. The Company considers market liquidity in determining the fair value for these securities. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three and nine months ended September 30, 2015 and 2014.

There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and nine months ended September 30, 2015 and 2014. 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 Avalanche common shares in January 2015. The Company's policy for recognition of transfers between levels of the fair value hierarchy is to recognize any transfer at the beginning of the fiscal quarter in which the determination to transfer was made. There were no other transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2015, and there were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2014.

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As of September 30, 2015 and December 31, 2014, the Company had $33.1 million and $169.4 million, respectively, in aggregate principal amount of 1.875% convertible senior notes (the "Notes") that will mature on October 1, 2016 unless earlier converted or repurchased. As described in Note 10, an additional portion of the Notes was surrendered for conversion during the first nine months of 2015. The fair value of the outstanding Notes was estimated to be $175.2 million and $819.8 million as of September 30, 2015 and December 31, 2014, respectively, and was determined based on Level 2 inputs, such as market and observable sources.

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

8. Inventories

Inventories consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Raw materials | $34,983 | $10,923 |
| Work-in-process | 110,616 | 73,519 |
| Finished goods | 12,513 | 10,768 |
| Deferred costs | 32,556 | 33,651 |
| | $190,668 | $128,861 |

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the three months ended September 30, 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $1.8 million and $1.6 million, respectively. For the nine months ended September 30, 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $9.9 million and $3.5 million, respectively.

9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Accounts payable | $106,917 | $99,508 |
| Accrued payroll and related costs | 120,933 | 92,778 |
| Accrued clinical trial expense | 62,569 | 41,555 |
| Accrued sales-related charges, deductions, and royalties | 160,941 | 133,085 |
| Other accrued expenses and liabilities | 126,068 | 116,563 |
| | $577,428 | $483,489 |

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10. Debt

a. Convertible Debt

In the first nine months of 2015, the Company settled conversion obligations for $146.0 million principal amount of the Company's Notes that was previously surrendered for conversion. In accordance with the terms of the Notes, the Company elected to settle these conversion obligations through a combination of cash, in an amount equal to the principal amount of the converted Notes, and shares of the Company's Common Stock in respect of any amounts due in excess thereof. Consequently, in the first nine months of 2015, 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 stockholders' equity, and recognized a $16.9 million loss on the debt extinguishment. As of September 30, 2015, an aggregate principal amount of $33.1 million of the original $400.0 million aggregate principal amount of Notes remained outstanding.

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

In addition to the Note conversions described above, the Company received notifications in the third and fourth quarters of 2015 that an additional $20.5 million aggregate principal amount of the Notes were surrendered for conversion, and settlement is anticipated during the fourth quarter of 2015. The Company has elected to settle the related conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, the Company exercised a proportionate amount of its convertible note hedges, for which the Company expects to receive shares of Common Stock equivalent to the number of shares the Company will be required to issue to settle the non-cash portion of the related Note conversions.

In the first nine months of 2014, the Company settled conversion obligations for $61.1 million principal amount of the Notes surrendered for conversion. Upon settlement of the Notes, which occurred during the second quarter of 2014, the Company paid $61.1 million in cash and issued 521,876 shares of Common Stock. In addition, during the second quarter of 2014, the Company allocated $156.7 million of the settlement consideration provided to the Note holders to the reacquisition of the equity component of the Notes, and recognized such amount as a reduction of stockholders' equity, and recognized a $10.8 million loss on the debt extinguishment. In connection with the Note conversions in the first nine months of 2014, the Company also exercised a proportionate amount of its convertible note hedges, for which the Company received 521,876 shares of Common Stock, which was equivalent 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 $43.8 million, as Treasury Stock during the first nine months of 2014.

In November 2014, the Company entered into an amendment agreement with a warrant holder whereby the parties agreed to reduce a portion of the number of warrants held by the warrant holder by up to a maximum of 493,229. The reduction in the number of warrants was determined based on the number of warrants with respect to which the warrant holder had closed out its hedge position, provided that the warrant holder did not effect any purchases at a price per share exceeding $397.75 per share, during the period starting on November 26, 2014 and ending no later than February 12, 2015. The Company was obligated to settle any payments due under the amendment agreement in

February 2015. Given that the amendment agreement contained a conditional obligation that required settlement in cash, and the Company's obligation was indexed to the Company's share price, the Company reclassified the estimated fair value of the 493,229 warrants from additional paid-in capital to a liability in November 2014, with such liability subsequently measured at fair value with changes in fair value recognized in earnings. As a result of the warrant holder closing out a portion of its hedge position prior to December 31, 2014, the Company recorded a $59.8 million accrued liability as of December 31, 2014 in connection with the warrant holder reducing the number of warrants it held. During the first quarter of 2015, the warrant holder closed out additional portions of its hedge position, and, as a result, in February 2015 the Company paid a total of $124.0 million to reduce the number of warrants held by such warrant holder by 416,480. Upon expiration of the November 2014 amended agreement, 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

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under the 2011 issuance. Total losses related to changes in fair value of the warrants during the first quarter of 2015 were not material.

In addition to the 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. As of September 30, 2015, an aggregate of 2,225,068 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

During the first nine months of 2014, the Company also entered into agreements to reduce the number of warrants held by warrant holders. Pursuant to the agreements, the Company paid an aggregate amount of $143.0 million to the warrant holders during 2014 to reduce the maximum number of shares of Common Stock issuable upon exercise of the warrants by 727,516 in the aggregate.

b. Credit Facility

In March 2015, the Company entered into an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes an option for the Company to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. Proceeds of the loans under the Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. The Credit Agreement also provides a $100.0 million sublimit for letters of credit. The Credit Agreement includes an option for the Company to elect to extend the maturity date of the Credit Facility beyond March 2020, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty.

Any loans under the Credit Facility have a variable interest rate based on either the London Interbank Offered Rate ("LIBOR") or an alternate base rate, plus an applicable margin that varies with the Company's debt rating and total leverage ratio. The Company had no borrowings outstanding under the Credit Facility as of September 30, 2015.

The Credit Agreement contains financial and operating covenants. Financial covenants include a maximum total leverage ratio and a minimum interest expense coverage ratio. The Company was in compliance with all covenants of the Credit Facility as of September 30, 2015.

11. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded an income tax provision in its Statement of Operations of $182.9 million and $98.4 million for the three months ended September 30, 2015 and 2014, respectively, and $516.7 million and $323.5 million for the nine months ended September 30, 2015 and 2014, respectively. The Company's effective tax rate was 46.5% and 54.1% for the three months ended September 30, 2015 and 2014, respectively, and 51.8% and 56.6% for the nine months ended September 30, 2015 and 2014, respectively. 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 (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-deductible Branded Prescription Drug Fee, and (iii) expiration, at the end of 2014, of the federal tax credit for increased research activities. The negative impact of these items was partly offset by the positive impact of the domestic manufacturing deduction.

The Company's effective tax rate for the three and nine months ended September 30, 2014 was negatively impacted, compared to the U.S. federal statutory rate, by losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, the incremental charge related to the non-tax deductible Branded Prescription Drug Fee (see Note 2),

and expiration at the end of 2013 of the federal tax credit for increased research activities. In addition, the Company's effective tax rate for the nine months ended September 30, 2014 was negatively impacted by New York State tax legislation enacted in the first quarter of 2014. This tax legislation reduced the New York State income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the Company reducing its related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in the Company's effective tax rate by 2.2% for the nine months ended September 30, 2014.

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The Company also recorded an income tax benefit in its Statement of Comprehensive Income of $6.5 million and $25.4 million for the three and nine months ended September 30, 2015, respectively, in connection with unrealized losses on available-for-sale marketable securities. The Company recorded an income tax provision in its Statement of Comprehensive Income of $13.5 million and $14.9 million for the three and nine months ended September 30, 2014, respectively, in connection with the Company's unrealized gains on available-for-sale marketable securities.

12. Statement of Cash Flows

Supplemental disclosure of non-cash investing and financing activities

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 September 30, 2014 and December 31, 2013 were $38.6 million and $16.1 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses as of September 30, 2015 and December 31, 2014 was $0.3 million and $7.5 million, respectively, for the Company's conversion settlement obligation related to the Company's Notes which were surrendered for conversion but not settled as of the end of the respective period. No such amounts were payable as of September 30, 2014 and December 31, 2013.

Included in accounts payable and accrued expenses as of December 31, 2014 was $59.8 million related to the Company's payment obligation for a reduction in the number of warrants based on a warrant holder closing out a portion of its hedge position. Additionally, included within other current liabilities as of December 31, 2014 was $87.5 million in connection with the estimated fair value of the remaining warrant liability. See Note 10. There were no such liabilities recorded in connection with warrants as of September 30, 2015, September 30, 2014, and December 31, 2013.

The Company recognized a facility lease obligation of $27.0 million and $92.6 million during the nine months ended September 30, 2015 and 2014, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

13. Legal Matters

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

Proceedings Relating to '287 Patent and '018 Patent

The Company is a party to patent infringement litigation involving its European Patent No. 1,360,287 and, with respect to certain defendants, also European Patent No. 2,264,163 (collectively, as applicable, the "'287 Patent"), as well as 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 "'287 Patent Infringement Litigation" and "'018 Patent Infringement Litigation," respectively), the Company claims infringement of several claims of the '287 Patent and the '018 Patent (as applicable), and seeks, among other types of relief, an injunction and an account of profits in connection with the defendants' infringing acts, which may include, among other things, the making, use, keeping, sale, or offer for sale of genetically engineered mice (or certain cells from which they are derived) that infringe one or more claims of the '287 Patent and the '018 Patent (as applicable). At this time, the Company is not able to predict the outcome of, or an estimate of gain, if any, related to, these proceedings.

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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, and 8,859,741 in the first complaint, U.S. Patent Nos. 8,871,913 and 8,871,914 in the second complaint, U.S. Patent No. 8,883,983 in the third complaint, and U.S. Patent No. 8,889,834 in the fourth complaint. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. On December 15, 2014, all of the four proceedings were consolidated into a single case. On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint. The complaint alleges, among other things, willful infringement of the asserted patents, which would entitle Amgen to treble damages if the court finds willful infringement. The Company and Sanofi have opposed the motion, and the parties are awaiting the court's decision on the motion. The trial is currently set to begin on March 7, 2016, and a permanent injunction hearing (which would be held if the court finds infringement by the Company and Sanofi) is currently scheduled to begin on March 23, 2016. This matter has not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to estimate a range of possible loss, if any.

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 (Los Angeles 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 in host cells. On the same day, the Company and Sanofi-Aventis U.S. LLC initiated an inter partes review in the United States Patent and Trademark Office seeking a declaration of invalidity of U.S. Patent No. 6,331,415 jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by the Company and Sanofi and counterclaimed, alleging that the Company and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016. At this time, the Company is not able to predict the outcome of these proceedings.

14. Recently Issued Accounting Standards

In May 2014, the FASB issued a new standard related to revenue recognition, Revenue from Contracts with Customers, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. 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 sarilumab, dupilumab, fasinumab, and REGN2222; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of our product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for marketed products, including without limitation Praluent® (alirocumab) Injection, sarilumab, dupilumab, fasinumab, and REGN2222; ongoing regulatory obligations and oversight impacting our marketed products (such as EYLEA® (aflibercept) Injection and Praluent), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our products and product candidates; competing drugs and product candidates that may be superior to our products and product candidates; uncertainty of market acceptance and commercial success of our products and product candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our sales or other financial projections or guidance, including without limitation capital expenditures and income tax obligations, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part II, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

Overview

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

Our total revenues were $1,137.4 million in the third quarter and $3,005.7 million in the first nine months of 2015, compared to $725.8 million in the third quarter and $2,017.2 million in the first nine months of 2014. Our net income was $210.4 million, or $1.82 per diluted share, in the third quarter and $481.1 million, or $4.18 per diluted share, in first nine months of 2015, compared to net income of $83.4 million, or $0.73 per diluted share, in the third quarter and $248.0 million, or $2.19 per diluted share, in the first nine months of 2014. Refer to the "Results of Operations" section below for further details of our financial results.

We currently have three marketed products:

- EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, is available in the United States, European Union (EU), Japan, and certain other countries outside the United States for the treatment of neovascular age-related macular degeneration (wet AMD), diabetic macular edema (DME), macular edema following central retinal vein occlusion (CRVO), and macular edema following retinal vein

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

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Praluent (alirocumab) Injection, which is available in the United States for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (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 (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 statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent.

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

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

We have 14 product candidates in clinical development, all of which were discovered in our research laboratories. These consist of a Trap-based clinical program and 13 fully human monoclonal antibody product candidates, as summarized below. Each of the antibodies in the table below was generated using our VelocImmune® technology.

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Trap-based Clinical Programs

EYLEA

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

Antibody-based Clinical Programs in Collaboration with Sanofi

Praluent

Antibody to PCSK9. In Phase 3 clinical development for LDL cholesterol reduction and for the prevention of cardiovascular events. In the third quarter of 2015, the U.S. Food and Drug Administration (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 the third quarter of 2015, the European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia. The effect of Praluent on cardiovascular morbidity and mortality has not been determined.

Sarilumab (REGN88)

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

Dupilumab (REGN668)

Antibody to the interleukin-4 receptor (IL-4R) alpha subunit. In clinical development in atopic dermatitis in adults (Phase 3), atopic dermatitis in children (Phase 2), asthma (Phase 3), nasal polyps in patients who also have chronic sinusitis (NPwCS) (Phase 2), and eosinophilic esophagitis (EoE) (Phase 2).

REGN2222

Antibody to the Respiratory Syncytial Virus-F (RSV-F) protein. Phase 3 clinical study in RSV initiated in the second quarter of 2015. In the fourth quarter of 2014, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN2222 effective December 2015, and will be entitled to receive royalties on any future sales of the product candidate.

REGN2810

Antibody to programmed cell death protein 1 (PD-1). Phase 1 clinical study in advanced malignancies initiated in the first quarter of 2015.

Antibody-based Clinical Program in Collaboration with Bayer HealthCare

REGN2176-3

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

Antibody-based Clinical Program in Collaboration with Mitsubishi Tanabe Pharma

Fasinumab (REGN475)*

Antibody to Nerve Growth Factor (NGF). Phase 2b/3 study in pain due to osteoarthritis initiated in the second quarter of 2015; currently on partial clinical hold by the FDA limiting duration of trials in osteoarthritis to 16 weeks.

Antibody-based Clinical Programs Developing Independently

Evinacumab (REGN1500)*

Antibody to Angptl-3. Phase 2 clinical study for the treatment of dyslipidemia in homozygous familial hypercholesterolemia initiated in the first quarter of 2015. Partial clinical hold that excluded women of childbearing potential was lifted by the FDA in the third quarter of 2015.

REGN1033*

Antibody to myostatin (GDF8). In Phase 2 clinical development in skeletal muscle disorders. In the second quarter of 2015, Sanofi provided notice to Regeneron that it had elected not to continue co-development of REGN1033.

REGN1908-1909*

Antibody to Feld1 in Phase 1/Phase 2 clinical development against allergic disease.

REGN1193*

Antibody to glucagon receptor (GCGR). In Phase 1 clinical development.

REGN1979

Bispecific antibody against CD20 and CD3. In Phase 1 clinical development for Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia.

REGN910-3**

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

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* Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive a mid-single digit royalty on future sales of the product candidate.
** We acquired from Sanofi full exclusive rights to antibodies targeting the Ang2 receptor and ligand in ophthalmology, which were previously included in our antibody collaboration with Sanofi. Under the terms of our agreement, Sanofi is entitled to receive a potential development milestone and royalties on any future sales of the product candidate.

REGN1400, an antibody to ErbB3, and REGN1154, an antibody against an undisclosed target, both of which were previously in Phase 1 studies, are no longer in clinical development.

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

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

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

Marketed Products

EYLEA (aflibercept) Injection

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

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

Net product sales of EYLEA in the United States were $734.4 million in the third quarter and $1,930.0 million in the first nine months of 2015, compared to $445.0 million in the third quarter and $1,218.8 million in the first nine months of 2014. Bayer HealthCare records revenue from sales of EYLEA outside the United States, which were $371.1 million in the third quarter and $1,000.7 million in the first nine months of 2015, compared to $277.0 million in the third quarter and $741.9 million in the first nine months of 2014.

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Praluent (alirocumab) Injection

In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In addition, in September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated statin, or (b) alone or in combination with other lipid-lowering therapies for patients who are statin intolerant, or for whom a statin is contraindicated. The effect of Praluent on cardiovascular morbidity and mortality has not been determined. We are collaborating with Sanofi on the global development and commercialization of Praluent. Under our collaboration agreement, Sanofi will record product sales and cost of sales for commercialized products, and Regeneron has the right to co-promote such products. We have exercised our option to co-promote Praluent in the United States. We and Sanofi will equally share profits and losses from sales within the United States.

Net product sales of Praluent in the United States were $4.0 million the third quarter 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 $3.2 million in the third quarter and $9.9 million in the first nine months of 2015, compared to $3.8 million in the third quarter and $10.4 million in the first nine months of 2014.

Trap-based Clinical Programs

EYLEA - Ophthalmologic Diseases

Overview

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

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

Neovascular Glaucoma

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

NVG meets the criteria for an orphan indication in Japan where the estimated number of NVG patients is 30,000 to 40,000. In the second quarter of 2015, Bayer HealthCare 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.

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Late-Stage Antibody-based Clinical Programs

Praluent for LDL cholesterol reduction

Overview

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

Clinical Programs

Phase 3 ODYSSEY Program. We and Sanofi initiated the global Phase 3 ODYSSEY program for Praluent in 2012. The ODYSSEY program consists of more than 23,500 patients, and includes clinical trials evaluating the effect of Praluent, dosed every two weeks, on lowering LDL cholesterol. In addition, the potential of Praluent to demonstrate cardiovascular benefit is being prospectively assessed in the ongoing 18,000-patient ODYSSEY OUTCOMES trial. LDL cholesterol reduction is the primary efficacy endpoint for initial regulatory filings. Additionally, the ODYSSEY program includes two trials of Praluent dosed every four weeks, ODYSSEY CHOICE I and ODYSSEY CHOICE II. Patients in the ODYSSEY CHOICE I trial received Praluent 300 mg (most in combination with statins) every four weeks and patients in the CHOICE II trial received Praluent 150 mg monotherapy and in combination with non-statin lipid lowering therapy every four weeks.

In 2013, we and Sanofi reported data from the ODYSSEY MONO trial, which evaluated the efficacy and safety of Praluent monotherapy versus ezetimibe monotherapy in patients with primary hypercholesterolemia. In 2014, we and Sanofi reported detailed positive results from nine additional Phase 3 ODYSSEY studies. All ten studies (ODYSSEY MONO, LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II, and ALTERNATIVE) met their primary efficacy endpoint of a greater percent reduction from baseline in LDL-C at 24 weeks compared to placebo or active comparator. Based on the positive results of these studies, a Biologics License Application (BLA) for U.S. regulatory approval of Praluent was submitted, and accepted by the FDA in January 2015. An FDA rare pediatric disease priority review voucher was utilized in connection with this BLA submission, as a result of which the submission was accepted by the FDA for priority review. In July 2015, the FDA approved Praluent as an adjunct to diet and maximally tolerated stain therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol. In addition, in September 2015, the European Commission granted marketing authorization of Praluent for the treatment of adult patients with primary hypercholesterolemia (HeFH and non-familial) or mixed dyslipidemia as an adjunct to diet: (a) in combination with a statin, or statin with other lipid-lowering therapies in patients unable to reach their LDL-cholesterol goals with the maximally-tolerated 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.

In January 2015, we and Sanofi announced that the ODYSSEY CHOICE I and ODYSSEY CHOICE II studies met their primary efficacy endpoints. The trials compared the reduction from baseline in LDL-C at 24 weeks with Praluent versus placebo in patients with hypercholesterolemia. In these trials dosing every four weeks, the mean percent reduction in LDL-C from baseline was consistent with that seen in previous Phase 3 trials evaluating Praluent in every other week dosing. The most common adverse events (AEs) in the trials (occurring in at least 5% of Praluent-treated patients) were injection site reactions, headache, upper respiratory tract infection, arthralgia, nausea, sinusitis, pain in extremity, and fatigue. Injection site reactions occurred more frequently in the Praluent groups compared to placebo.

In July 2015, we and Sanofi announced that the Phase 3 ODYSSEY JAPAN trial met its primary endpoint. At week 24, patients in the Praluent group experienced an average 64% greater reduction from baseline in their LDL-C when added to current standard of care including statins, compared to standard of care alone ($p<0.0001$). Patients were started on the lower dose of 75 mg, with the option to adjust their dose to 150 mg if they had not achieved their LDL-C goal (as defined by the Japan Atherosclerosis Society (JAS) guidelines) at week 8. At week 24, 97% of patients in the Praluent group reached their LDL-C treatment goal, compared to 10% for placebo ($p<0.0001$). Ninety-nine percent of patients who received Praluent at week 8 remained on the initial 75 mg dose, while 1% of patients had their dose adjusted to receive 150 mg every two weeks, also as a single 1 milliliter (mL) injection. The most common adverse events (occurring in at least 5% of patients in the Praluent group) were nasopharyngitis, injection site reaction, and back pain. Results were presented at the Annual Scientific Meeting of the JAS in Sendai, Japan.

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ODYSSEY JAPAN evaluated Praluent (n =144) compared to placebo (n =72), both on top of standard care, in Japanese patients with hypercholesterolemia, with either HeFH or at high CV risk, and who could not reach their LDL-C treatment goal as defined by the JAS guidelines despite lipid-lowering treatments that included statins. The mean LDL-C value at baseline was 141.2 mg/dL. Patients were initially randomized to receive either Praluent 75 mg every two weeks administered as a single 1 mL injection, or placebo. Patients in both groups received statins, with or without other lipid-lowering therapies.

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. In 2013, we and Sanofi announced 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. Additional data from the trial were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2015. A summary of primary endpoints and most common AEs for this trial, as well as additional Phase 3 trials, is as follows:

Completed Efficacy and Safety Studies

| Study | Patient group | Primary efficacy endpoints | | | Safety findings |
|---|---|---|---|---|---|
| | | ACR[a] 20/50/70 | HAQ-DI[b] | mTSS[c] | |
| MOBILITY (n=1,197) | | | | | |
| 150mg + MTX (n=400) | | 58/37/20 (p<0.0001 vs. placebo) | -0.53 | 0.90 | |
| 200mg + MTX (n=398) | Moderate to severe RA with inadequate response to MTX | 66/46/25 (p<0.0001 vs. placebo) | -0.55 | 0.25 | Infections, neutropenia, injection site reactions, and increased transaminases |
| Placebo + MTX (n=399) | | 33/17/7 | -0.29 | 2.78 | |
| TARGET (n=546) | | 56/37[e]/20[f] | -0.50 | | |
| 150mg + DMARD[d] (n=181) | Moderate to severe active RA with inadequate response to, or intolerant of, one or more tumor necrosis factor-alpha (TNF-alpha) inhibitors | 61/41[e]/16[f] | -0.49 | | |
| 200mg + DMARD (n=181) | | 34/18/7 | -0.29 | NA | Infections, neutropenia, injection site reactions, and hypertriglyceridemia |
| Placebo + DMARD (n=184) | | | | | |

NA = not applicable
a.ACR = American College of Rheumatology score
b.HAQ-DI = the Health Assessment Question-Disability Index
c.mTSS = van der Heijde modified total Sharp score
d.DMARD = non-biologic disease modifying anti-rheumatic drugs
e.p<0.0001 vs. placebo
f.p<0.025 vs. placebo

Completed Safety Studies

| Study | Patient group | Primary endpoint | Study met primary endpoint? |
|---|---|---|---|

| | | | |
|---|---|---|---|
| ASCERTAIN (n=202) | Moderate to severe active RA with inadequate response to, or intolerant of, one or more TNF-alpha inhibitors | Assess safety of two subcutaneous doses of sarilumab and tocilizumab in combination with DMARDs | Yes |
| EASY (n=217) | Completed patients from MOBILITY, TARGET, or ASCERTAIN trials | Product technical failures | Yes |

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Detailed results from the SARIL-RA-TARGET, SARIL-RA-EASY, and SARIL-RA-ASCERTAIN trials will be presented at the upcoming annual meeting of the American College of Rheumatology and other medical congresses. We and Sanofi have also initiated additional Phase 3 studies, SARIL-RA-ONE, SARIL-RA-MONARCH, and SARIL-RA-KAKEHASI (in Japan). In addition, the SARIL-RA-HARUKA long-term safety trial was initiated in Japan in the first quarter of 2015. In the second quarter of 2015, an open-label, randomized, parallel group, single-dose Phase 1 study to assess the safety of IL-6 receptor blockade with sarilumab or tocilizumab monotherapy in Japanese patients with RA was also initiated. The broad SARIL-RA clinical development program is focused on adult populations with moderate-to-severe RA who are inadequate responders to either MTX or tumor necrosis factor alpha inhibitor therapy. Patients who complete SARIL-RA-MOBILITY, SARIL-RA-TARGET, SARIL-RA-ASCERTAIN, or SARIL-RA-ONE are offered enrollment into the ongoing SARIL-RA-EXTEND, which is an open-label, long-term safety study of sarilumab.

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. The primary endpoint of the study was the proportion of patients with a 2-step decrease in vitreous haze (based on a 9-point grading scale) or a steroid dose of less than 10 mg/day at week 16. Results of this study at the pre-specified primary endpoint, week 16, showed that compared with placebo patients, a greater proportion of patients randomized to sarilumab met the primary endpoint; however, this was not statistically significant. Approximately 70% of patients enrolled in the study had a baseline vitreous haze score of less than 2 as judged by the reading center, limiting our ability to interpret the vitreous haze component of the primary endpoint for these patients. Other indications of a positive effect of treatment with sarilumab compared to placebo included decreased average vitreous haze score, reduced macular edema and improved best-corrected visual acuity in patients presenting with more severe baseline ocular inflammation, and associated with improvement of leakage on fluorescein angiography. Overall, safety observations were consistent with the findings in studies of other indications with sarilumab. The study is ongoing and will continue through week 52, when we will discuss next steps with our collaborator Sanofi.

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

Overview

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

Atopic Dermatitis

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

- 12% to 33% of dupilumab-treated patients achieved clearing or near-clearing of skin lesions, as measured by an Investigator's Global Assessment (IGA) score of 0 or 1, compared to 2% with placebo ($p=0.02$ to $p<0.0001$).
-

Dupilumab-treated patients experienced a 16.5% to 47% mean reduction in itching, as measured by the pruritus numerical-rating scale (NRS) score, compared to an increase of 5% in the placebo group (p=0.0005 to p<0.0001). This Phase 2b double-blind, placebo-controlled, 16-week, dose-ranging study randomized 380 patients with moderate-to-severe atopic dermatitis, who could not be adequately controlled with topical medication or for whom topical treatment was not advisable. Patients were randomized to receive one of five doses of dupilumab (300 mg weekly, 300 mg every other week, 300 mg monthly, 200 mg every other week, 100 mg monthly) or placebo. Patients in the study had approximately 50% of their skin affected by

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atopic dermatitis at baseline. In the year preceding enrollment in the study, approximately 35% of patients received an oral corticosteroid and approximately 20% received a systemic non-steroid immunosuppressant for atopic dermatitis. Approximately 60% of patients had another allergic condition, including approximately 40% of patients who had a history of asthma.

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

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

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

Asthma

Phase 2b Study. In May 2015, we and Sanofi presented positive results from an interim analysis of a pivotal Phase 2b study of dupilumab in adult patients with moderate-to-severe asthma, who are uncontrolled despite treatment with inhaled corticosteroids and long-acting beta agonists (ICS/LABA), at the American Thoracic Society 2015 International Conference. As previously reported in 2014, the study met its primary endpoint of improving lung function in asthma patients with high blood eosinophil counts ((HEos), greater than or equal to 300 eosinophilic cells/microliter). New data presented on secondary endpoints at the American Thoracic Society 2015 International Conference included positive results in study patients with low blood eosinophil counts ((LEos), less than 300 eosinophilic cells/microliter), who are thought to be less likely to suffer from "allergic" asthma and thus less likely to respond to Type 2 helper T-cell (TH2) targeted therapies. Based on discussions with the FDA, this Phase 2b study may be considered one of two pivotal efficacy studies required for a potential dupilumab BLA in asthma.

The results presented in May 2015 focused on LEos asthma patients. In this population, patients treated every other week with either 200 mg or 300 mg doses of dupilumab showed a greater than 8% improvement in forced expiratory volume over one second ((FEV1), a standard measure of lung function) at week 12 ($p<0.001$), in comparison to placebo, both in combination with ICS/LABA. Additionally, the 200 mg and 300 mg every other week doses of dupilumab in combination with ICS/LABA showed 68% and 62% reductions, respectively, in adjusted annualized rate of severe exacerbations in the LEos population ($p<0.01$ and $p<0.05$), in comparison to placebo in combination with ICS/LABA. These results are consistent with previously reported positive results in HEos asthma patients and the overall patient population, in which the two every other week doses (200 mg and 300 mg) of dupilumab in combination with ICS/LABA demonstrated a statistically significant 12% to 15% improvement in FEV1 over placebo at week 12 and a 64% to 75% improvement in annualized rate of severe exacerbations over placebo. Dupilumab also significantly reduced mean fractional exhaled nitric oxide (FeNO) across both every other week doses tested (200 mg and 300 mg) and the three patient populations (overall, LEos and HEos), in a roughly dose-dependent manner. FeNO is recommended by the American Thoracic Society clinical practice guidelines to assess airway inflammation, since higher-than-normal levels of nitric oxide may be released when a patient has a chronic airway disease, such as asthma. The most common AE was injection site reaction, which was more frequent in the dupilumab dose groups (13% to 25%) compared to placebo (12%). Other common AEs in the study included upper respiratory tract infection (10% to 13% dupilumab; 13% placebo), headache (5% to 10% dupilumab; 8% placebo), nasopharyngitis (3% to 10% dupilumab; 6% placebo) and bronchitis (5% to 8% dupilumab; 8% placebo). The incidence of infections was balanced

across treatment groups (42% to 45% dupilumab; 46% placebo), as was the incidence of serious AEs (3% to 7% dupilumab; 5% placebo).

These results were based on a pre-specified interim analysis, which occurred when all patients had reached week 12 of the 24-week treatment period; the average treatment duration at the time of the analysis was 21.4 weeks. The primary endpoint of the study was improvement from baseline in FEV1 at week 12 in the HEos group. Final analyses on exacerbations and safety will be conducted after 24 weeks of treatment and a 16-week follow-up period.

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

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controlled Phase 3 study is expected to enroll more than 1,600 patients with uncontrolled persistent asthma and will evaluate two doses of dupilumab, 200 mg and 300 mg, subcutaneously administered every other week.

Nasal Polyposis

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

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

Eosinophilic Esophagitis

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

REGN2222 (RSV-F Antibody) for RSV

Overview

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

Clinical Program

Based on clinical results from a Phase 1 study, and following discussions with the FDA, REGN2222 entered into a Phase 3 pivotal clinical study (NURSERY Pre-Term) in the third quarter of 2015. NURSERY Pre-Term is a two part study, and Part A is currently enrolling patients in the Southern hemisphere. Part A is an open-label pharmacokeninetic study, which is designed to enable dose selection for Part B; Part B is expected to commence later this year in the Northern Hemisphere.

Fasinumab (REGN475; NGF Antibody) for pain due to osteoarthritis

Overview

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

Clinical Program

A Phase 2b/3 clinical study in patients with pain due to osteoarthritis was initiated in the second quarter of 2015. Fasinumab is currently on partial clinical hold by the FDA, limiting duration of trials in osteoarthritis to 16 weeks.

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Research Programs

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

In September 2015, we and the Biomedical Advanced Research and Development Authority (BARDA) of the U.S. Department of Health and Human Services (HHS) entered into an agreement to develop, test, and manufacture a monoclonal antibody therapy for the treatment of Ebola virus infection. HHS will provide initial funding of approximately $17.0 million to support our preclinical development and antibody manufacturing. HHS also has the option to provide for up to an additional $32.2 million for a Phase 1 study in healthy volunteers, and further manufacturing and development studies.

Research and Development Technologies

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

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

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

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

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

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

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

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

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 collaboration, Sanofi was responsible for funding up to $160.0 million per year of our antibody discovery activities over the period from 2010-2014, and, as amended in connection with the companies' July 2015 immuno-oncology collaboration as described below, is funding up to $145.0 million in 2015, and up to $130.0 million in each of 2016 and 2017 to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Our discovery activities to identify and validate potential drug discovery targets in the field of immuno-oncology and develop fully human monoclonal antibodies against these targets will now be funded by Sanofi under the terms of the companies' new immuno-oncology collaboration. We lead the design and conduct of research activities under the Antibody Discovery Agreement, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. Sanofi has an option to extend certain antibody development and preclinical activities relating to selected program targets for up to an additional three years after 2017.

For each drug candidate identified through discovery research under the 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 up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by Sanofi and 20% by us. We are generally responsible for reimbursing Sanofi for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs.

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

outside the United States exceed $1.0 billion on a rolling 12-month basis.

Immuno-Oncology. In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (IO Discovery Agreement), and an Immuno-oncology License and Collaboration Agreement (IO License and Collaboration Agreement). In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable upfront 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, which consists of (i) $750.0 million in new funding and (ii) $75.0 million of funding that would have otherwise been available to Regeneron under the existing Antibody Discovery

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Agreement, as described above. The term of the IO Discovery Agreement will continue through the later of five years from the effective date of the IO Collaboration or the date the IO Discovery Budget is exhausted, subject to Sanofi's option to extend it for up to an additional three years for the continued development (and funding) of selected ongoing programs. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of IND Applications, and clinical development through proof-of-concept. 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. However, we are not required to apply more than 10% of our share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. 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 (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable upfront 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, subject to the same 10% reimbursement limitation described above. 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. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

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

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, we or Sanofi may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

ZALTRAP. Since September 2003, we and Sanofi have been parties to a global collaboration (ZALTRAP Collaboration Agreement) for the development and commercialization of ZALTRAP. In February 2015, we and Sanofi entered into an Amended ZALTRAP Agreement. Under the terms of the Amended ZALTRAP Agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP for cancer indications worldwide. Sanofi bears the cost of all development and commercialization activities and reimburses Regeneron for

its costs for any such activities. Sanofi pays us a percentage of aggregate net sales of ZALTRAP during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of ZALTRAP in such calendar year. We will also be paid for all quantities of ZALTRAP manufactured by us pursuant to a supply agreement through the earlier of 2021 or the date Sanofi receives regulatory approval to manufacture ZALTRAP at one of its facilities or a facility of a third party. In addition, Regeneron no longer has a contingent contractual obligation (which was approximately $461 million at December 31, 2014) to reimburse Sanofi for 50% of the development expenses that Sanofi previously funded for the development of ZALTRAP under the ZALTRAP Collaboration Agreement.

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Collaborations with Bayer HealthCare

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

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

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

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

PDGFR-beta antibody outside the United States. In January 2014, we entered into an agreement with Bayer HealthCare governing the joint development and commercialization outside the United States of an antibody product candidate to PDGFR-beta, including in combination with EYLEA, for the treatment of ocular diseases or disorders. REGN2176-3, a combination product candidate comprised of an antibody to PDGFR-beta co-formulated with EYLEA, is being developed under the agreement. Under the agreement, we will conduct the initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, upon which Bayer HealthCare will have a right to opt-in to license and collaborate on further development and commercialization outside the United States.

In connection with the agreement, Bayer HealthCare made a $25.5 million non-refundable upfront payment to us in January 2014, and is obligated to pay 25% of global development costs and 50% of development costs exclusively for the territory outside the United States under the initial development plan. In addition, Bayer HealthCare is obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made two $2.5 million development milestone payments to us in the 2014, and an additional $5.0 million development milestone payment to us in the second quarter of 2015. Further, in connection with our initial development of the PDGFR-beta antibody through completion of the first proof-of-concept study, we are eligible to receive up to $10.0 million in future development milestone payments from Bayer HealthCare, although certain of these development milestone payments could be reduced by half if Bayer HealthCare does not opt-in to the collaboration.

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

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

We also have the right to opt-out of the collaboration upon completion of the first proof-of-concept study for the PDGFR-beta antibody. If we opt-out of the collaboration and Bayer HealthCare exercises its right to opt-in to the collaboration, Bayer HealthCare will obtain exclusive rights to the PDGFR-beta antibody (except as a combination

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

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

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the agreement, MTPC made a $10.0 million non-refundable upfront payment, and we are entitled to receive up to an aggregate of $215.0 million in development milestone and other contingent payments.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Unless terminated earlier in accordance with its provisions, the agreement will continue to be in effect until such time as MTPC has ceased developing or commercializing fasinumab in the MTPC Territories.

General

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

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

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The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2015 to date were, and plans for the next twelve months are, as follows:

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

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Antibody-based Clinical Programs:

| | 2015 Events to Date | 2015-2016 Plans (next 12 months) |
|---|---|---|
| Praluent (PCSK9 Antibody) | BLA accepted for priority review in the United States<br>Regulatory application accepted for review by the EMA<br>Reported positive results from ODYSSEY CHOICE I and CHOICE II trials<br>ODYSSEY LONG TERM 18-month trial results published in The New England Journal of Medicine<br>Reported positive results from ODYSSEY Japan trial<br>FDA approved Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol<br>European Commission granted marketing authorization for Praluent for the treatment of LDL cholesterol in certain adult patients with hypercholesterolemia | Complete patient enrollment of Phase 3 ODYSSEY OUTCOMES trial<br>Report additional results from Phase 3 ODYSSEY trials<br>File for additional regulatory approvals outside the United States<br>Regulatory agency decisions on applications outside the United States |
| Sarilumab (IL-6R Antibody) | Initiated and completed patient enrollment in Phase 3 MONARCH study (head-to-head monotherapy study against adalimumab)<br>Initiated several studies in Japan<br>Reported positive results from SARIL-RA-TARGET, SARIL-RA-EASY, and SARIL-RA-ASCERTAIN trials<br>Completed patient enrollment in SARIL-NIU-SATURN Phase 2 study in non-infectious uveitis and reported top-line results<br>BLA submitted in the United States | Continue patient enrollment in Phase 3 SARIL-RA program<br>Report results from additional Phase 3 trials<br>Regulatory agency decision on application for U.S. approval |
| Dupilumab (IL-4R Antibody) | Initiated Phase 2 study in EoE<br>Initiated and completed enrollment for Phase 2 study in atopic dermatitis in adolescents and children<br>Initiated Phase 3 study in asthma<br>Presented positive pivotal Phase 2b data in asthma at the American | Continue patient enrollment in various Phase 2 and Phase 3 studies<br>Complete patient enrollment in Phase 2 EoE and Phase 3 asthma studies |

| | | |
|---|---|---|
| | Thoracic Society 2015 International Conference<br>Completed patient enrollment in Phase 3 atopic dermatitis pivotal trials | |
| REGN2222 (RSV-F Antibody) | Completed Phase 1 study | Continue patient enrollment in Part A of Phase 3 NURSERY Pre-Term study |
| | Initiated Part A of Phase 3 NURSERY Pre-Term study | Initiate Part B of Phase 3 NURSERY Pre-Term study |
| Fasinumab (NGF Antibody) | Initiated sixteen-week Phase 2b/3 study in osteoarthritis | Complete patient enrollment in Phase 2b/3 study |
| | On partial clinical hold by the FDA | Initiate full development program pending removal of partial clinical hold |

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Antibody-based Clinical Programs (continued):

| | 2015 Events to Date | 2015-2016 Plans (next 12 months) |
|---|---|---|
| Evinacumab (Angptl-3 Antibody) | Initiated Phase 2 study<br>Partial clinical hold lifted by the FDA | Complete patient enrollment in Phase 1 and Phase 2 studies |
| REGN1033 (GDF8 Antibody) | Phase 2 proof-of-concept study in elderly men and women with sarcopenia met its primary endpoint, while secondary, functional endpoints were mixed.<br>Sanofi elected not to continue co-development | Determine future development plan |
| REGN1908-1909 (Feld1 Antibody) | Completed patient enrollment in Phase 2 study | |
| REGN2176-3 (PDGFR-beta Antibody co-formulated with aflibercept) | Received Fast Track designation from the FDA for the treatment of patients with wet AMD<br>Initiated Phase 2 study | Continue patient enrollment in Phase 2 study |
| REGN1193 (GCGR Antibody) | Continued patient enrollment in Phase 1 study | Complete patient enrollment in Phase 1 study |
| REGN1979 (CD20 and CD3 Antibody) | Continued patient enrollment in Phase 1 study | Complete patient enrollment in Phase 1 study |
| REGN910-3 (Ang2 Antibody co-formulated with aflibercept) | Completed patient enrollment in Phase 1 study | |
| REGN2810 (PD-1 Antibody) | Initiated Phase 1 study | Continue patient enrollment in Phase 1 study |

Corporate Information

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

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

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

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Results of Operations

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

Three Months Ended September 30, 2015 and 2014

Net Income

Net income for the three months ended September 30, 2015 and 2014 consists of the following:

| (In millions) | 2015 | 2014 |
|---|---|---|
| Revenues | $1,137.4 | $725.8 |
| Operating expenses | (745.0) | (537.3) |
| Other income (expense) | 0.9 | (6.6) |
| Income before income taxes | 393.3 | 181.9 |
| Income tax expense | (182.9) | (98.5) |
| Net income | $210.4 | $83.4 |

Revenues

Revenues for the three months ended September 30, 2015 and 2014 consist of the following:

| (In millions) | 2015 | 2014 |
|---|---|---|
| Net product sales | $737.6 | $448.8 |
| Collaboration revenue: | | |
| Sanofi | 224.7 | 132.9 |
| Bayer HealthCare | 157.6 | 135.9 |
| Total collaboration revenue | 382.3 | 268.8 |
| Technology licensing and other revenue | 17.5 | 8.2 |
| Total revenues | $1,137.4 | $725.8 |

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. We received marketing approval from the FDA for EYLEA for the treatment of wet AMD in 2011, macular edema following CRVO in 2012, DME in July 2014, macular edema following BRVO in October 2014, and diabetic retinopathy in patients with DME in March 2015. For the three months ended September 30, 2015, EYLEA net product sales increased to $734.4 million from $445.0 million for the three months ended September 30, 2014 due to higher sales volume. For the three months ended September 30, 2015 and 2014, we also recognized ARCALYST net product sales of $3.2 million and $3.8 million, respectively.

For the three months ended September 30, 2015 and 2014, we recorded 65% and 72%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

Revenue from product sales is recorded net of applicable provisions for rebates and chargebacks under governmental programs, 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, 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 |
| | | | | |
| Balance as of June 30, 2014 | $4.1 | $20.4 | $0.5 | $25.0 |
| Provision related to current period sales | 8.5 | 17.5 | 0.4 | 26.4 |
| Credits/payments | (8.8) | (19.4) | (0.4) | (28.6) |
| Balance as of September 30, 2014 | $3.8 | $18.5 | $0.5 | $22.8 |

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, under the companies' Antibody Collaboration.

| Sanofi Collaboration Revenue | Three Months Ended September 30, | |
|---|---|---|
| (In millions) | 2015 | 2014 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | $205.1 | $140.5 |
| Reimbursement of Regeneron commercialization-related expenses | 53.3 | 1.7 |
| Regeneron's share of losses in connection with commercialization of antibodies | (74.9) | (12.8) |
| Other | 2.6 | 2.5 |
| Total Antibody | 186.1 | 131.9 |
| Immuno-oncology: | | |
| Reimbursement of Regeneron research and development expenses | 18.6 | — |
| Other | 20.0 | — |
| Total Immuno-oncology | 38.6 | — |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | — | (1.0) |
| Reimbursement of Regeneron research and development expenses | — | 1.3 |
| Other | — | 0.7 |
| Total ZALTRAP | — | 1.0 |
| Total Sanofi collaboration revenue | $224.7 | $132.9 |

In the third quarter of 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of $42.5 million under our Antibody Discovery Agreement and $162.6 million under our License and Collaboration Agreement, compared to $47.9 million and $92.6 million, respectively, in the third quarter of 2014. The higher reimbursement of research and development costs in the third quarter of 2015, compared to the same period in 2014, was primarily due to increased development activities for dupilumab.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with commercialization of Praluent and sarilumab. Effective in the second and fourth quarters of 2014, we and Sanofi

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began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement. Consequently, we began recording our share of losses in connection with commercialization of Praluent and sarilumab. Sanofi provides us with an estimate of our share of the profit or loss from commercialization 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.

Following the FDA approval in July 2015, sales of Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol, commenced in the United States. Praluent net product sales, which are recorded by Sanofi, were $4.0 million in the third quarter of 2015. We and Sanofi incurred higher commercialization expenses for Praluent primarily in connection with launching the product in the United States.

Other Sanofi antibody revenue includes recognition of deferred revenue from an $85.0 million up-front payment and other payments. As of September 30, 2015, $64.9 million of the up-front and other payments was deferred and will be recognized as revenue in future periods.

In July 2015, we and Sanofi entered into a global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (as described above under "Collaboration Agreements - Collaboration with Sanofi - Immuno-Oncology"). In the third quarter of 2015, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $12.8 million under our IO Discovery Agreement and $5.8 million under our IO License and Collaboration Agreement.

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, 2015, $620.0 million of the up-front payments was deferred and will be recognized ratably as revenue in future periods.

In September 2003, we and Sanofi entered into a ZALTRAP Collaboration Agreement to jointly develop and commercialize ZALTRAP. Under the terms of ZALTRAP Collaboration Agreement, we and Sanofi shared profits and losses on sales of ZALTRAP outside of Japan, and we were entitled to receive a percentage of sales of ZALTRAP in Japan. Our share of the loss in connection with the commercialization of ZALTRAP in the third quarter of 2014 represents our share of the costs of launching and commercializing ZALTRAP, partly offset by net product sales. As described above under "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP" and below in the "Nine Months Ended September 30, 2015 and 2014" section, in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement.

Bayer HealthCare Collaboration Revenue

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

| Bayer HealthCare Collaboration Revenue | Three Months Ended September 30, | |
|---|---|---|
| (In millions) | 2015 | 2014 |
| EYLEA: | | |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $130.5 | $85.4 |
| Sales milestones | — | 30.0 |
| Cost-sharing of Regeneron EYLEA development expenses | 1.8 | 4.4 |
| Other | 21.2 | 12.7 |
| Total EYLEA | 153.5 | 132.5 |
| PDGFR-beta antibody: | | |
| Cost-sharing of REGN2176-3 development expenses | 1.5 | 0.5 |
| Other | 2.6 | 2.9 |
| Total PDGFR-beta antibody | 4.1 | 3.4 |
| Total Bayer HealthCare collaboration revenue | $157.6 | $135.9 |

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

| Regeneron's Net Profit from EYLEA Sales Outside the United States | Three Months Ended September 30, | |
|---|---|---|
| (In millions) | 2015 | 2014 |
| Net product sales outside the United States | $371.1 | $277.0 |
| Regeneron's share of collaboration profit from sales outside the United States | $144.2 | $99.8 |
| Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation | (13.7) | (14.4) |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $130.5 | $85.4 |

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

In the third quarter of 2014, we earned two $15.0 million sales milestone payment from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $800 million and $900 million, respectively, over a twelve-month period.

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States and reimbursements for producing EYLEA commercial supplies for Bayer HealthCare. In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare. As of September 30, 2015, $11.8 million of the EYLEA up-front and 2007 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration Agreements - Collaborations with Bayer HealthCare - PDGFR-beta antibody outside the United States." Other PDGFR-beta antibody revenue consists of recognition of deferred revenue related to the PDGFR-beta up-front payment and non-substantive milestones received in the first quarter of 2014. As of September 30, 2015, $12.1 million of the PDGFR-beta up-front and 2014 milestone payments was deferred and will be recognized ratably as revenue in future periods.

Technology Licensing and Other Revenue

In connection with the amendment and extension of our VelocImmune license agreement with Astellas, in August 2010, we received a $165.0 million up-front payment, which was deferred upon receipt and is being recognized as revenue ratably over a seven-year period beginning in June 2011. In the third quarter of both 2015 and 2014, we recognized $5.9 million of revenue related to this agreement. As of September 30, 2015, $63.3 million of the August 2010 technology licensing payment received from Astellas was deferred and will be recognized as revenue in future periods.

In connection with the February 2015 Amended ZALTRAP Agreement with Sanofi, we recorded $9.0 million of revenue in the third quarter of 2015 primarily related to manufacturing ZALTRAP commercial supplies for Sanofi and the percentage of net sales of ZALTRAP Sanofi is obligated to pay us.

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris (canakinumab). In the third quarter of 2015 and 2014, technology licensing and other revenue included $2.6 million

and $1.9 million, respectively, of royalties from Novartis.

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Expenses

Total operating expenses increased to $745.0 million in the third quarter of 2015 from $537.3 million in the third quarter of 2014. Our average headcount in the third quarter of 2015 increased to 3,966 from 2,714 in the same period in 2014, principally in connection with expanding our research and development and commercialization activities. Operating expenses in the third quarter of 2015 and 2014 included a total of $102.6 million and $68.1 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 2015 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2014 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $425.9 million in the third quarter of 2015 from $337.7 million in the same period of 2014. 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) | 2015 | 2014 | (Decrease) |
| Payroll and benefits [1] | $129.2 | $99.2 | $30.0 |
| Clinical trial expenses | 81.2 | 46.7 | 34.5 |
| Clinical manufacturing costs [2] | 121.0 | 72.0 | 49.0 |
| Research and other development costs | 33.4 | 58.1 | (24.7) |
| Occupancy and other operating costs | 33.5 | 29.1 | 4.4 |
| Cost-sharing of Bayer HealthCare and Sanofi development expenses [3] | 27.6 | 32.6 | (5.0) |
| Total research and development expenses | $425.9 | $337.7 | $88.2 |

[1] Includes Non-cash Compensation Expense of $52.8 million for the three months ended September 30, 2015 and $39.0 million for the three months ended September 30, 2014.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Also includes Non-cash Compensation Expense of $10.8 million for the three months ended September 30, 2015 and $7.1 million for the three months ended September 30, 2014.

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

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to additional costs for clinical studies of dupilumab and fasinumab, partly offset by lower REGN1033- and EYLEA-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of dupilumab and sarilumab. Research and other development costs decreased primarily due to our 50% share ($33.8 million) of the cost of purchasing a FDA priority review voucher in the third quarter of 2014 for use with the Praluent BLA filing, partly offset by higher expenditures in connection with our expanded research 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 HealthCare and Sanofi, the portion of Bayer HealthCare 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) | 2015 | 2014 | (Decrease) |
| Praluent | $64.0 | $105.1 | $(41.1) |
| Dupilumab | 101.5 | 36.2 | 65.3 |
| Sarilumab | 29.2 | 21.7 | 7.5 |
| EYLEA | 15.6 | 27.8 | (12.2) |
| Other antibody candidates in clinical development | 67.7 | 65.4 | 2.3 |
| Other research programs and unallocated costs | 147.9 | 81.5 | 66.4 |
| Total research and development expenses | $425.9 | $337.7 | $88.2 |

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 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 $210.0 million in the third quarter of 2015 from $144.0 million in the third quarter of 2014 primarily due to higher headcount and related costs, higher Non-cash Compensation Expense principally for the reason described under "Expenses" above and higher commercialization expenses related to Praluent, partly offset by lower costs associated with the Branded Prescription Drug Fee as

described below. Selling, general, and administrative expenses included $36.5 million and $21.2 million of Non-cash Compensation Expense in the third quarter of 2015 and 2014, respectively.

Selling, general, and administrative expenses in the third quarter of 2014 included a $40.6 million incremental charge related to the Branded Prescription Drug Fee, which is a non-tax deductible annual fee (the Branded Prescription Drug Fee) imposed on

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pharmaceutical manufacturers that sell branded prescription drugs to specified government programs. In July 2014, the Internal Revenue Service (IRS) issued final regulations that provide guidance on the Branded Prescription Drug Fee. The final regulations differ in some respects from the temporary regulations previously issued by the IRS in 2011, including that a company is liable for the fee based on its branded prescription drug sales in the current year, instead of the liability only being applicable upon the first qualifying branded prescription drug sale of the following fee year under the temporary regulations. As a result of the issuance of these final IRS regulations, we began recording an estimate of the fee in the same period in which our qualifying branded prescription drug sales occur. Therefore, in the third quarter of 2014, an incremental charge was recorded to (i) recognize a liability for the estimated fee payable based on 2014 sales through the first nine months of 2014, and (ii) expense the remaining prepaid asset recorded under the previous accounting for the estimated fee payable based on 2013 sales.

Cost of Goods Sold

Cost of goods sold was $67.2 million in the third quarter of 2015 and $33.7 million in the third quarter of 2014. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold increased principally due to the increase in U.S. EYLEA net product sales.

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 HealthCare, increased to $41.9 million in the third quarter of 2015 from $21.9 million in the third quarter of 2014. This increase was primarily due to royalties payable to Genentech in connection with higher sales of EYLEA outside the United States, as well as the recognition of costs associated with commercial supplies of EYLEA manufactured for Bayer HealthCare.

Other Income and Expense

Total other income (net of other expenses) was $0.9 million in the third quarter of 2015 and total other expenses (net of other income) was $6.6 million in the third quarter of 2014. Interest expense in the third quarter of 2015 decreased compared to the third quarter of 2014 primarily due to conversions of a substantial principal amount of our 1.875% convertible senior notes (the Notes) since the third quarter of 2014.

Income Taxes

In the third quarter of 2015 and 2014, we recorded income tax expense of $182.9 million and $98.4 million, respectively. The effective tax rate was 46.5% and 54.1% for the third quarter of 2015 and 2014, respectively. The third quarter 2015 effective tax rate was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-tax deductible Branded Prescription Drug Fee, and (iii) 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 effective tax rate for the third quarter of 2014 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 incremental charge related to the non-tax deductible Branded Prescription Drug Fee (as described above), and expiration at the end of 2013 of the federal tax credit for increased research activities.

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Nine Months Ended September 30, 2015 and 2014

Net Income

Net income for the nine months ended September 30, 2015 and 2014 consists of the following:

| (In millions) | 2015 | 2014 |
|---|---|---|
| Revenues | $3,005.7 | $2,017.2 |
| Operating expenses | (1,984.9) | (1,409.1) |
| Other income (expense) | (23.0) | (36.6) |
| Income before income taxes | 997.8 | 571.5 |
| Income tax expense | (516.7) | (323.5) |
| Net income | $481.1 | $248.0 |

Revenues

Revenues for the nine months ended September 30, 2015 and 2014 consist of the following:

| (In millions) | 2015 | 2014 |
|---|---|---|
| Net product sales | $1,940.0 | $1,229.2 |
| Collaboration revenue: | | |
| Sanofi | 593.2 | 406.0 |
| Bayer HealthCare | 415.7 | 358.5 |
| Total collaboration revenue | 1,008.9 | 764.5 |
| Technology licensing and other revenue | 56.8 | 23.5 |
| Total revenues | $3,005.7 | $2,017.2 |

Net Product Sales

Net product sales consist of U.S. sales of EYLEA and ARCALYST. For the nine months ended September 30, 2015, EYLEA net product sales increased to $1,930.0 million from $1,218.8 million for the nine months ended September 30, 2014 due to higher sales volume. For the nine months ended September 30, 2015 and 2014, we also recognized ARCALYST net product sales of $9.9 million and $10.4 million, respectively.

For the nine months ended September 30, 2015 and 2014, we recorded 67% and 75%, respectively, of our total gross product revenue from sales to Besse Medical, a subsidiary of AmerisourceBergen Corporation.

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

| (In millions) | Rebates & Chargebacks | Distribution-Related Fees | Other Sales-Related Deductions | Total |
|---|---|---|---|---|
| Balance as of December 31, 2014 | $3.1 | $21.2 | $0.5 | $24.8 |
| Provision related to current period sales | 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 |
| | | | | |
| Balance as of December 31, 2013 | $4.4 | $19.7 | $0.5 | $24.6 |
| Provision related to current period sales | 23.3 | 53.7 | 1.2 | 78.2 |
| Credits/payments | (23.9) | (54.9) | (1.2) | (80.0) |
| Balance as of September 30, 2014 | $3.8 | $18.5 | $0.5 | $22.8 |

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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, under the companies' Antibody Collaboration.

| Sanofi Collaboration Revenue | Nine Months Ended September 30, | |
|---|---|---|
| (In millions) | 2015 | 2014 |
| Antibody: | | |
| Reimbursement of Regeneron research and development expenses | $585.5 | $405.2 |
| Reimbursement of Regeneron commercialization-related expenses | 89.1 | 7.0 |
| Regeneron's share of losses in connection with commercialization of antibodies | (143.6) | (17.1) |
| Other | 7.7 | 7.7 |
| Total Antibody | 538.7 | 402.8 |
| Immuno-oncology: | | |
| Reimbursement of Regeneron research and development expenses | 18.6 | — |
| Other | 20.0 | — |
| Total Immuno-oncology | 38.6 | — |
| ZALTRAP: | | |
| Regeneron's share of losses in connection with commercialization of ZALTRAP | — | (4.9) |
| Reimbursement of Regeneron research and development expenses | 0.7 | 3.7 |
| Other | 15.2 | 4.4 |
| Total ZALTRAP | 15.9 | 3.2 |
| Total Sanofi collaboration revenue | $593.2 | $406.0 |

In the first nine months of 2015, Sanofi's reimbursement of our antibody research and development expenses consisted of $145.0 million under our Antibody Discovery Agreement and $440.5 million under our License and Collaboration Agreement, compared to $131.0 million and $274.2 million, respectively, in the first nine months of 2014. The higher reimbursement of research and development costs in the first nine months of 2015, compared to the same period in 2014, was primarily due to increased research and pre-clinical activities under our Antibody Discovery Agreement and increased development activities for dupilumab, REGN2222, and Praluent.

Reimbursement of Regeneron commercialization-related expenses represents reimbursement of internal and external costs in connection with commercialization of Praluent and sarilumab. Effective in the second and fourth quarters of 2014, we and Sanofi began sharing pre-launch commercial expenses related to Praluent and sarilumab, respectively, in accordance with the companies' License and Collaboration Agreement (and, accordingly, we began recording our share of losses in connection with commercialization of Praluent and sarilumab). Sanofi provides us with an estimate of our share of the profit or loss from commercialization 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.

Following the FDA approval in July 2015, sales of Praluent for the treatment of adults with heterozygous familial hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL cholesterol, commenced in the United States. Praluent net product sales, which are recorded by Sanofi, were $4.0 million in the third quarter of 2015. We and Sanofi incurred higher commercialization expenses for Praluent in the first nine months of 2015 primarily in connection with preparing for and launching the product in the United States.

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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 (as described above under "Collaboration Agreements - Collaboration with Sanofi - Immuno-Oncology"). In the third quarter of 2015, Sanofi's reimbursement of our immuno-oncology research and development expenses consisted of $12.8 million under our IO Discovery Agreement and $5.8 million under our IO License and Collaboration Agreement.

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.

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

As described above under "Collaboration Agreements - Collaborations with Sanofi - ZALTRAP," in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi which amended and restated the ZALTRAP Collaboration Agreement. As a result, in the first quarter of 2015 we recognized $14.9 million of previously deferred revenue under the ZALTRAP Collaboration Agreement, related to (i) amounts that were previously reimbursed by Sanofi for manufacturing commercial supplies of ZALTRAP since our risk of inventory loss under the collaboration no longer existed, and (ii) the unamortized portion of up-front payments from Sanofi as we had no further performance obligations.

Bayer HealthCare Collaboration Revenue

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

| Bayer HealthCare Collaboration Revenue | Nine Months Ended September 30, | |
|---|---|---|
| (In millions) | 2015 | 2014 |
| EYLEA: | | |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $326.6 | $213.3 |
| Sales milestones | 15.0 | 75.0 |
| Cost-sharing of Regeneron EYLEA development expenses | 6.9 | 26.2 |
| Other | 50.7 | 34.5 |
| Total EYLEA | 399.2 | 349.0 |
| PDGFR-beta antibody: | | |
| Cost-sharing of REGN2176-3 development expenses | 8.7 | 1.7 |
| Other | 7.8 | 7.8 |
| Total PDGFR-beta antibody | 16.5 | 9.5 |
| Total Bayer HealthCare collaboration revenue | $415.7 | $358.5 |

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) | Nine Months Ended September 30, 2015 | 2014 |
|---|---|---|
| Net product sales outside the United States | $1,000.7 | $741.9 |
| Regeneron's share of collaboration profit from sales outside the United States | $368.1 | $256.8 |
| Reimbursement of EYLEA development expenses incurred by Bayer HealthCare in accordance with Regeneron's payment obligation | (41.5) | (43.5) |
| Regeneron's net profit in connection with commercialization of EYLEA outside the United States | $326.6 | $213.3 |

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

In the first nine months of 2015, we earned a $15.0 million sales milestone payment from Bayer HealthCare upon total aggregate net sales of specific commercial supplies of EYLEA outside the United States exceeding $200 million over a twelve-month period. In the first nine months of 2014, we earned five $15.0 million sales milestone payments from Bayer HealthCare upon total aggregate net sales of EYLEA outside the United States exceeding $500 million, $600 million, $700 million, $800 million, and $900 million, respectively, over a twelve-month period.

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

Other EYLEA revenue primarily consists of reimbursement of other Regeneron EYLEA expenses, principally related to Bayer HealthCare's share of royalties payable to Genentech pursuant to a license and settlement agreement in connection with sales of EYLEA outside the United States and reimbursements for producing EYLEA commercial supplies for Bayer HealthCare. In addition, other EYLEA revenue includes recognition of deferred revenue related to EYLEA up-front and 2007 non-substantive milestone payments from Bayer HealthCare.

Cost-sharing of REGN2176-3 development expenses with Bayer HealthCare commenced in the first quarter of 2014 following the execution of the companies' PDGFR-beta antibody collaboration agreement as described above under "Collaboration Agreements - Collaborations with Bayer HealthCare - PDGFR-beta antibody outside the United States." Bayer HealthCare is also obligated to reimburse us for 50% of development milestone payments to Sanofi related to our acquisition of rights to antibodies targeting the PDGF family of receptors in May 2013. In that regard, Bayer HealthCare made a $5.0 million development milestone payment to us in the second quarter of 2015, which was recognized as revenue in the second quarter and included in "Cost-sharing of REGN2176-3 development expenses" in the table above.

Technology Licensing and Other Revenue

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

recognized $17.7 million of revenue related to this agreement.

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

In addition, under a June 2009 agreement with Novartis, we receive royalties on worldwide sales of Novartis' Ilaris. In the first nine months of 2015 and 2014, technology licensing and other revenue included $7.0 million and $5.4 million, respectively, of royalties from Novartis.

Expenses

Total operating expenses increased to $1,984.8 million in the first nine months of 2015 from $1,409.1 million in the first nine months of 2014. Our average headcount in the first nine months of 2015 increased to 3,535 from 2,551 in the same period in 2014, principally in connection with expanding our research and development and commercialization activities.

Operating expenses in the first nine months of 2015 and 2014 included a total of $300.7 million and $208.7 million, respectively, of Non-cash Compensation Expense. The increase in total Non-cash Compensation Expense in the first nine months of 2015 was primarily attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2014 compared to recent prior years.

Research and Development Expenses

Research and development expenses increased to $1,159.4 million in the first nine months of 2015 from $919.6 million in the same period of 2014. The following table summarizes the major categories of our research and development expenses:

| Research and Development Expenses | Nine Months Ended September 30, | | Increase |
|---|---|---|---|
| (In millions) | 2015 | 2014 | (Decrease) |
| Payroll and benefits [1] | $365.9 | $288.6 | $77.3 |
| Clinical trial expenses | 212.2 | 147.5 | 64.7 |
| Clinical manufacturing costs [2] | 306.0 | 191.5 | 114.5 |
| Research and other development costs | 98.6 | 110.4 | (11.8) |
| Occupancy and other operating costs | 97.6 | 85.6 | 12.0 |
| Cost-sharing of Bayer HealthCare and Sanofi development expenses [3] | 79.1 | 96.0 | (16.9) |
| Total research and development expenses | $1,159.4 | $919.6 | $239.8 |

[1] Includes Non-cash Compensation Expense of $154.2 million for the nine months ended September 30, 2015 and $113.9 million for the nine months ended September 30, 2014.

[2] Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, as well as pre-launch commercial supplies which were not capitalized as inventory. Includes related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, drug filling, packaging, and labeling costs, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Also includes Non-cash Compensation Expense of $28.9 million for the nine months ended September 30, 2015 and $19.3 million for the nine months ended September 30, 2014.

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

Payroll and benefits increased principally due to the increase in employee headcount and Non-cash Compensation Expense, as described above. Clinical trial expenses increased primarily due to additional costs for clinical studies of dupilumab and fasinumab, partly offset by lower Praluent-, EYLEA-, and REGN1033-related costs. Clinical manufacturing costs increased primarily due to additional costs related to manufacturing drug supplies of dupilumab,

Praluent, sarilumab, and, to a lesser extent, several other antibody product candidates.

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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 HealthCare and Sanofi, the portion of Bayer HealthCare 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) | 2015 | 2014 | (Decrease) |
| Praluent | $195.2 | $222.5 | $(27.3) |
| Dupilumab | 269.2 | 118.7 | 150.5 |
| Sarilumab | 67.4 | 65.4 | 2.0 |
| EYLEA | 52.4 | 89.0 | (36.6) |
| Other antibody candidates in clinical development | 191.4 | 149.1 | 42.3 |
| Other research programs and unallocated costs | 383.8 | 274.9 | 108.9 |
| Total research and development expenses | $1,159.4 | $919.6 | $239.8 |

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2015 and 2014, 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 $543.6 million in the first nine months of 2015 from $344.0 million in the first nine months of 2014 primarily due to higher headcount and related costs, higher Non-cash Compensation Expense principally for the reason described under "Expenses" above, and higher commercialization-related expenses related to Praluent. Selling, general, and administrative expenses included $110.8 million and $73.6 million of Non-cash Compensation Expense in the first nine months of 2015 and 2014, respectively.

Cost of Goods Sold

Cost of goods sold was $170.6 million in the first nine months of 2015 and $91.1 million in the first nine months of 2014. Cost of goods sold primarily consists of royalties, as well as costs in connection with producing U.S. EYLEA commercial supplies and various start-up costs in connection with our Limerick, Ireland commercial manufacturing facility. Cost of goods sold increased principally due to the increase in U.S. EYLEA net product sales. In addition, in the first nine months of 2015 and 2014, cost of goods sold included inventory write-downs and reserves totaling $9.9 million and $3.5 million, respectively.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing, which includes costs we incur in connection with producing commercial drug supplies for Sanofi and Bayer HealthCare, increased to $111.3 million in the first nine months of 2015 from $54.5 million in the first nine months of 2014. This increase was primarily due to the recognition of costs associated with commercial supplies of ZALTRAP, as well as royalties payable to Genentech in connection with higher sales of EYLEA outside the United States and the recognition of costs associated with commercial supplies of EYLEA manufactured for Bayer HealthCare. Under our collaboration arrangements, when the product is sold by our collaborators to third-party customers, our risk of inventory loss no longer exists, and we therefore recognize our related manufacturing costs for the sold product as cost of collaboration manufacturing. However, as described above, in February 2015, we entered into an Amended ZALTRAP Agreement with Sanofi. As a result, in the first quarter of 2015 we recognized as expense $20.2 million of previously inventoried costs for ZALTRAP commercial supplies that were shipped to Sanofi because our risk of inventory loss no longer exists under the Amended ZALTRAP Agreement.

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Other Income and Expense

Total other expenses (net of other income) decreased to $23.0 million in the first nine months of 2015 from $36.6 million in the first nine months of 2014. Interest expense in the first nine months of 2015 decreased compared to the first nine months of 2014 primarily due to conversions of a substantial principal amount of our Notes since the third quarter of 2014. In addition, in the first nine months of 2015 and 2014, we recognized a $16.9 million and a $10.8 million loss, respectively, in connection with Notes which were surrendered for conversion during the respective periods.

Income Taxes

In the first nine months of 2015 and 2014, we recorded income tax expense of $516.7 million and $323.5 million, respectively. The effective tax rate was 51.8% for the first nine months of 2015 and 56.6% for the first nine months of 2014. The effective tax rate for the first nine months of 2015 was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the U.S. federal statutory rate, (ii) the non-tax deductible Branded Prescription Drug Fee, and (iii) 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 effective tax rate for the first nine months of 2014 was negatively impacted, compared to the U.S. federal statutory rate, by (i) losses incurred in foreign jurisdictions with rates lower than the federal statutory rate, (ii) expiration at the end of 2013 of the federal tax credit for increased research activities, (iii) the incremental charge related to the non-tax deductible Branded Prescription Drug Fee (as described above), and (iv) New York State tax legislation enacted in the first quarter of 2014. This tax legislation reduced the New York State income tax rate to zero percent for "qualified manufacturers," including Regeneron, effective in 2014; however, it also resulted in the reduction of our related deferred tax assets as a discrete item in the first quarter of 2014. As a result, this tax legislation caused a net increase in our effective tax rate by 2.2% for the first nine months of 2014.

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Liquidity and Capital Resources

The sources and uses of cash discussion below reflects certain revisions to previously-issued financial statements. See Notes 1 and 4 of the Notes to Condensed Consolidated Financial Statements for a description of such revisions.

Sources and Uses of Cash for the Nine Months Ended September 30, 2015 and 2014

As of September 30, 2015, we had $1,577.0 million in cash, cash equivalents, and marketable securities compared with $1,360.6 million as of December 31, 2014. Additionally, as of September 30, 2015, 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 $1,049.0 million in the first nine months of 2015. Our net income of $481.1 million in the first nine months of 2015 included Non-cash Compensation Expense of $300.7 million and depreciation and amortization of $52.0 million. In addition, deferred tax assets as of September 30, 2015 increased by $66.0 million, compared to December 31, 2014, primarily due to an increase in Non-cash Compensation Expense, partly offset by an increase in deferred tax liabilities associated with earnings of foreign subsidiaries.

As of September 30, 2015, Sanofi, Bayer HealthCare, 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 $81.5 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 upfront 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.

Net cash provided by operating activities was $554.3 million in the first nine months of 2014. Our net income of $248.0 million in the first nine months of 2014 included Non-cash Compensation Expense of $208.7 million and depreciation and amortization of $38.6 million. In addition, deferred tax assets as of September 30, 2014 increased by $34.2 million, compared to end-of-year 2013, primarily due to an increase in Non-cash Compensation Expense and a credit for alternative minimum tax paid, partly offset by the reduction of our deferred tax assets related to the New York State tax legislation enacted in the first quarter of 2014, which reduced our New York State income tax rate to zero percent effective in 2014.

As of September 30, 2014, Sanofi, Bayer HealthCare, and trade accounts receivable decreased by $53.6 million, compared to December 31, 2013, primarily due to lower trade accounts receivable resulting from shortened payment terms to certain of our U.S. EYLEA customers effective January 2014, partly offset by higher amounts receivable from Bayer HealthCare in connection with the commercialization of EYLEA outside the United States. Inventories increased by $50.9 million, compared to December 31, 2013, primarily in connection with increased production of EYLEA commercial supplies. Accounts payable, accrued expenses, and other liabilities increased by $76.5 million at September 30, 2014, compared to December 31, 2013, primarily due to higher accruals for sales-related charges, including the impact of the Branded Prescription Drug Fee incremental charge as described above, and higher accruals related to various clinical studies and capital expenditures.

Cash Used in Investing Activities

Net cash used in investing activities was $784.3 million and $477.4 million in the first nine months of 2015 and 2014, respectively. In the first nine months of 2015 and 2014, purchases of marketable securities exceeded sales or maturities by $284.1 million and $262.0 million, respectively. Capital expenditures were $500.2 million and $215.5 million in the first nine month of 2015 and 2014, respectively. 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 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. We intend to develop this property to accommodate and support our growth, primarily in connection with expanding our existing research and development and office space. Capital expenditures in the first nine months of 2014 primarily included costs in connection with expanding our Rensselaer, New York manufacturing facilities, tenant improvement and associated costs related to our leased facilities in Tarrytown, New York, and the acquisition and renovations of our Limerick, Ireland manufacturing facility.

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Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $258.8 million in the first nine months of 2015 and net cash provided by financing activities was $34.1 million in the first nine months of 2014. In the first nine months of 2015, proceeds in connection with facility and capital leases obligations primarily relates to reimbursements of $27.4 million we received from our landlord for tenant improvement costs in connection with our leased facilities in Tarrytown, New York. In the first nine months of 2015 and 2014, $146.0 million and $61.1 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 2015 and 2014, we paid an aggregate amount of $523.5 million and $143.0 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 $150.4 million in the first nine months of 2015, compared to $80.8 million in the first nine months of 2014. In addition, payments for employee tax obligations in connection with stock option exercises and vesting of restricted stock were $71.7 million in the first nine months of 2015 compared to $175.9 million in the first nine months of 2014. Cash flows from financing activities also increased by $305.6 million and $334.1 million in the first nine months of 2015 and 2014, respectively, due to utilization of excess tax benefits in connection with stock option exercises, which offset cash tax obligations.

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, 2015.

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, 2015.

Immuno-Oncology Collaboration with Sanofi

As described above under "Collaboration Agreements - Collaborations with Sanofi," 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 is governed by an IO Discovery Agreement and an IO License and Collaboration Agreement. In connection with the IO Discovery Agreement, Sanofi made a $265.0 million non-refundable upfront payment to us. Pursuant to the IO Discovery Agreement, we will spend up to $1,090.0 million 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 of these costs, subject to certain annual limits (including an annual limit of $55.0 million in 2015), to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept. Pursuant to the IO Discovery Agreement, we will be primarily responsible for the design and conduct of all research activities, including target identification and validation, antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of IND Applications, and clinical development through proof-of-concept. 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. However, we are not required to apply more than 10% of our share of the profits from IO Collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. 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 (as further described below). If Sanofi does not exercise its option to license rights to a product candidate, we will retain the exclusive right to develop and commercialize such product candidate and Sanofi will be entitled to receive a royalty on sales.

In connection with the IO License and Collaboration Agreement, Sanofi made a $375.0 million non-refundable upfront 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

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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, subject to the same 10% reimbursement limitation described above. 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. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products. We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the IO License and Collaboration Agreement until commercial supplies of that IO drug candidate are being manufactured.

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

Fasinumab Collaboration with Mitsubishi Tanabe Pharma

As described above under "Collaboration Agreements - Collaborations with Mitsubishi Tanabe Pharma," in September 2015, we and MTPC entered into a collaboration agreement providing MTPC with development and commercial rights to fasinumab in Japan and certain other countries in Asia. In connection with the agreement, MTPC made a $10.0 million non-refundable upfront payment, and we are entitled to receive up to an aggregate of $65.0 million in development milestones achieved by us and $150.0 million in other contingent payments, primarily related to development milestones achieved by MTPC.

Under the agreement, we are obligated to manufacture and supply MTPC with clinical and commercial supplies of fasinumab. If fasinumab is commercialized in the MTPC Territories, we will supply the product to MTPC at a tiered purchase price, which ranges from 30% to 50% of net sales of the product (subject to adjustment in certain circumstances), and are eligible for additional payments up to an aggregate of $100.0 million upon the achievement of specified annual net sales amounts starting at $200 million.

Tarrytown, New York Lease

In April 2013, we entered into a new lease agreement for approximately 297,000 square feet of additional new laboratory and office space to be constructed in two new buildings (the Buildings), which was completed in the third quarter of 2015, at our current Tarrytown, New York location. The term of the lease, which commenced during the second half of 2014, is approximately 15 years and contains three renewal options to extend the term of the lease by five years each. The lease provides for (i) monthly payments over its term, which will commence in the fourth quarter of 2015 and will be based on the landlord's costs of construction and tenant allowances, and (ii) additional charges for utilities, taxes, and operating expenses. Based upon various factors, including our involvement in the Buildings' construction and our responsibility for directly paying for a substantial portion of tenant improvements, we are deemed, in substance, to be the owner of the landlord's Buildings in accordance with the application of Financial Accounting Standards Board (FASB) authoritative guidance. Consequently, in addition to capitalizing the tenant improvements, we capitalize the landlord's costs of constructing these new facilities, offset by a corresponding facility lease obligation. In addition, we recognize, as additional facility lease obligation, reimbursements from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation. We will allocate a portion of our future lease payments to the Buildings and the land on which the Buildings were constructed. The land element of the lease is

treated for accounting purposes as an operating lease. As of September 30, 2015 and December 31, 2014, the Buildings' facility lease obligation balance was $207.1 million and $152.8 million, respectively.

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Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled $500.2 million in the first nine months of 2015 and $215.5 million in the first nine months of 2014 (as described under "Cash Used in Investing Activities" above). We expect to incur capital expenditures of approximately $125 million to $175 million in the fourth quarter of 2015 primarily in connection with renovating our new Limerick, Ireland facility, tenant improvements primarily related to the Buildings at our leased Tarrytown, New York facilities, and expanding and renovating a portion of our manufacturing facilities at our Rensselaer, New York facility.

Funding Requirements

We expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical testing), capital expenditures, costs related to the preparation for potential commercialization of our late-stage antibody product candidates, and commercialization of EYLEA and Praluent. We believe that our existing capital resources, borrowing availability under our revolving credit facility, funds generated by anticipated EYLEA net product sales, and, as described above under "Collaboration Agreements," funding for reimbursement of research and development costs that we are entitled to receive under our collaboration agreements with Sanofi and Bayer HealthCare, will enable us to meet our projected operating needs for the foreseeable future.

Under our Antibody Collaboration with Sanofi and our collaboration with Bayer HealthCare for EYLEA outside the United States, we and our collaborator share profits and losses in connection with commercialization of drug products. Profits or losses under each collaboration are measured by calculating net sales less cost of goods sold and shared commercialization and other expenses. If the applicable collaboration is profitable, we have contingent contractual obligations to reimburse Sanofi and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses funded by Sanofi and Bayer HealthCare. These reimbursements would be deducted each quarter, in accordance with a formula, from our share of the collaboration profits (and, for our EYLEA collaboration with Bayer HealthCare, our percentage on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. In particular, as of December 31, 2014, our contingent reimbursement obligation to Bayer HealthCare for EYLEA was approximately $262 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately $1,308 million. Therefore, we expect that, for the foreseeable future, a portion of our share of profits from sales of EYLEA outside the United States and a portion of our share of profits, if any, from sales of Praluent will be used to reimburse our collaborator for this obligation.

We enter into research collaboration and licensing agreements that may require us to pay amounts upon the achievement of various development and commercial milestones, which, in the aggregate, could be significant. For example, in May 2013, we acquired from Sanofi full exclusive rights to antibodies targeting the PDGF family of receptors and ligands in ophthalmology and all other indications; consequently, we are obligated to pay up to $20.0 million in potential additional development milestones as well as royalties on any future sales of PDGF antibodies. Additionally, if required by the agreement, we may be required to make royalty payments 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.

The amount we need to fund operations will depend on various factors, including revenues from net product sales, the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations (in particular those with Sanofi and Bayer HealthCare). Clinical trial costs are dependent, among other things, on the size and duration of trials, 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. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we

decide to initiate, and the various factors that affect the cost of each trial as described above.

In addition to our anticipated commercialization costs for EYLEA and Praluent, our 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 some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on sales of certain commercial 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 additional royalties or share the profits from such sales pursuant to our license or collaboration agreements. In addition, under the provisions of the PPACA and the Health Care and Education Reconciliation Act of 2010, the Branded Prescription Drug Fee is imposed on pharmaceutical manufacturers that sell branded

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prescription drugs to specified government programs. This fee is allocated to companies, including Regeneron, based on their market share of total branded prescription drug sales into these government programs.

As described above, in the first nine months of 2015 and 2014, we made cash payments of $71.7 million and $175.9 million, respectively, for employee tax obligations in connection with stock option exercises and vesting of restricted stock. Future cash requirements for such payments will depend on various factors, including the level of stock option grants and exercises and the sales prices of our Common Stock, and may continue to be substantial.

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

In the third and fourth quarters of 2015, we received notifications that an additional $20.5 million aggregate principal amount of our Notes were surrendered for conversion, and settlement is anticipated during the fourth quarter of 2015. We elected to settle these conversion obligations through a combination of cash and shares (total payment will be based on the average of the volume-weighted-average prices of the Common Stock during the 40 trading-day cash settlement averaging period specified in the indenture governing the Notes). In connection with these Note conversions, we exercised a proportionate amount of our Note hedges, for which we expect to receive shares of Common Stock approximately equal to the number of shares we will be required to issue to settle the non-cash portion of the related Note conversions. In future periods, other holders of these debt securities may surrender their Notes for conversion.

We may also from time to time seek to repurchase or retire our outstanding Notes, or other outstanding securities, through cash purchases or exchanges for other securities, in open market purchases, privately negotiated transactions, or otherwise.

Due primarily to the amounts of our tax credit carry-forwards available for tax purposes, which totaled approximately $146 million as of December 31, 2014, and potential excess tax benefits in connection with stock option exercises, we expect our cash income tax payments for 2015 to be significantly less than the income tax expense recorded in our financial statements in 2015, which is based on an effective tax rate. However, we expect our cash income tax payments in 2015 to be substantially higher than such payments in 2014.

Future Impact of Recently Issued Accounting Standards

In May 2014, the FASB issued a new standard related to revenue recognition, Revenue from Contracts with Customers, which will replace existing revenue recognition guidance. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. 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 interim and annual 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. We have not yet determined our method of transition and are evaluating the impact that this guidance will have on our financial statements.

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, 2014 (filed February 12, 2015). There have been no material changes to our market risks or to our management of such risks as of September 30, 2015.

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 (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.

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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, 2015 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, 2014 (filed February 12, 2015), our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015 (filed May 7, 2015), our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015 (filed August 4, 2015), 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 '018 Patent

As previously reported, we are parties to patent infringement litigation involving our European Patent No. 1,360,287 (the '287 Patent) and our U.S. Patent No. 8,502,018 (the '018 Patent), both of which concern genetically altered mice capable of producing chimeric antibodies that are part human and part mouse.

On October 19, 2015, following the grant of our European Patent No. 2,264,163 (the '163 Patent) by the European Patent Office, we added an infringement claim based on the '163 Patent to our '287 Patent infringement litigation against Kymab Ltd and Novo Nordisk A/S in the English High Court of Justice, Chancery Division, Patents Court, in London (previously consolidated into a single case). Both Kymab and Novo Nordisk counterclaimed alleging invalidity of the '163 Patent. A trial to adjudicate the claims of infringement and invalidity of the '287 Patent and the '163 Patent is currently set to begin in the week of November 16, 2015.

On November 2, 2015, the United States District Court for the Southern District of New York issued an opinion and order in our '018 Patent infringement litigation against Merus B.V. finding that the '018 Patent was procured by inequitable conduct, thus rendering it unenforceable. We plan to appeal the court's order.

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. On September 15, 2015, Amgen filed a motion for leave to file a supplemental and second amended complaint. The complaint alleges, among other things, willful infringement of the asserted patents, which would entitle Amgen to treble damages if the court finds willful infringement. We and Sanofi have opposed the motion, and the parties are awaiting the court's decision on the motion. The trial is currently set to begin on March 7, 2016, and a permanent injunction hearing (which would be held if the court finds infringement by us and Sanofi) is currently scheduled to begin on March 23, 2016.

Proceedings Relating to Patents Owned by Genentech and City of Hope

As previously reported, we and Sanofi-Aventis U.S. LLC are parties to litigation concerning U.S. Patent No. 7,923,221 (the '221 Patent), which is jointly owned by Genentech, Inc. and City of Hope and relates to the production of recombinant antibodies in host cells. On September 17, 2015, Genentech and City of Hope answered the complaint previously filed by us and Sanofi and counterclaimed, alleging that we and Sanofi infringe the '221 Patent and seeking, among other types of relief, damages and a permanent injunction. On November 2, 2015, the court set a tentative trial date beginning on September 27, 2016.

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.

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Risks Related to Commercialization of EYLEA

We are substantially dependent on the success of EYLEA. If we or Bayer HealthCare 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, 2015 and 2014, EYLEA net sales in the United States represented 64% and 60% of our total revenues, respectively. If we were to experience difficulty with the commercialization of EYLEA in the United States, if Bayer HealthCare were to experience any difficulty with the commercialization of EYLEA outside the United States, or if we and Bayer HealthCare are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed.

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

- effectiveness of the commercial strategy in and outside the United States for the marketing of EYLEA, including pricing strategy and the continued effectiveness of efforts to obtain, and the timing of obtaining, adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for EYLEA with third parties who perform fill/finish or other steps in the manufacture of EYLEA to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of EYLEA;
- our ability to effectively communicate to the marketplace the benefits of the dosing regimen of EYLEA as compared to the dosing regimen of Lucentis® (ranibizumab), and the willingness of retinal specialists and patients to switch from Lucentis or off-label use of repackaged Avastin® (bevacizumab) to 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; and
- 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.

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

We and Bayer HealthCare are subject to significant ongoing regulatory obligations and oversight with respect to EYLEA. If we or Bayer HealthCare 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 HealthCare 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 HealthCare 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.

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

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

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

Our sales in the United States of EYLEA are dependent, in large part, on the availability and extent of reimbursement from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid. Sales of EYLEA in other countries are dependent, in large part, on similar programs in those countries. In the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs, including limiting federal healthcare expenditures. 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. 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. Novartis and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of wet AMD, macular edema following RVO, DME, visual impairment due to mCNV, diabetic retinopathy in patients with DME, and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD, in June 2010 for the treatment of macular edema following RVO (including CRVO and BRVO), in August 2012 for the treatment of DME, and in February 2015 for the treatment of diabetic retinopathy in patients with DME. Lucentis was also approved by the EMA for wet AMD in January 2007, for DME in January 2011, for the treatment of macular edema following RVO (including CRVO and BRVO) in June 2011, and for mCNV in July 2013. 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'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.

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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 ESBA1008 (RTH258), 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 (ESBA1008) 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 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 (currently in a Phase 2 trial in patients with wet AMD). Competitors are also developing eye-drop formulations, oral therapies, and gene/cell therapies for various indications that, if approved, would compete with EYLEA in one or more of its currently approved indications.

In addition, ophthalmologists are using with success 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 well exacerbate the competitive challenge which EYLEA faces in this or other eye indications for which it may be 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 HealthCare 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 outside the United States.

Under the terms of our license and collaboration agreement with Bayer HealthCare (which is terminable by Bayer HealthCare at any time upon six or twelve months' advance notice), we rely on Bayer HealthCare for sales, marketing, and distribution of EYLEA in countries outside the United States. If we and Bayer HealthCare 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 HealthCare 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 HealthCare, see "Risks Related to Our Reliance on Third Parties - If our collaboration with Bayer HealthCare for EYLEA is terminated, or Bayer HealthCare 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.

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Sales of EYLEA recorded by us and Bayer HealthCare 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 HealthCare'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 HealthCare, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer HealthCare. 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 HealthCare's sales, thereby adversely affecting our results of operations. In addition, there have been proposals to legalize the import of pharmaceuticals from outside the United States. If such legislation were enacted, our future revenues derived from EYLEA sales could be reduced.

Risks Related to Commercialization of Praluent

If we and 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 effectively communicate to the marketplace the benefits of Praluent;
- 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;
- our and Sanofi's ability to maintain sales of Praluent in the face of competitive products, including those currently in clinical development;
- the impact of post-approval studies of Praluent (including the ongoing ODYSSEY OUTCOMES trial prospectively assessing the potential of Praluent to demonstrate cardiovascular benefit), whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about Praluent (or data about products similar to Praluent that implicate an entire class of products or are perceived to do so);
- our ability to meet the demand for commercial supplies of Praluent;
- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including reporting and disclosure requirements of such laws and regulations and the potential impact of such requirements on physician prescription practices; and
- 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.

More detailed information about the risks related to the commercialization of Praluent is provided 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

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

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

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

Sales of Praluent are dependent on the availability and extent of reimbursement from third-party payers, 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 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. 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, or the eligible insured patient population for Praluent is limited, 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, 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 approval from the FDA and marketing authorization from the European Commission for its PCSK9 inhibitor Repatha™ (evolocumab). Amgen may obtain marketing approval for Repatha in one or more additional countries before Praluent is approved in those countries.

Several other companies, including Pfizer, also have development programs for antibodies against PCSK9. Alnylam, in partnership 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 an oral product. 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'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. Another oral agent that lowers LDL-C and that may potentially compete with Praluent is Esperion's ETC-1002.

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

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

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

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

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

In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings,

precautions, or contra-indications with respect to conditions of use. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible

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that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

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

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

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

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

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly likely to be a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. In addition,

actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities often also have the authority to require post-approval studies, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

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

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

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

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

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

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

future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

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

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

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

EYLEA is being studied in diseases of the eye in addition to those covered by its currently approved indications and 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 EYLEA. 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 EYLEA (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 EYLEA.

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 has been 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, 2014. 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 under the America Invents Act of 2011. We expect that post-grant review proceedings will become common in the United States and will be 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, 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 and our U.S. Patent No. 8,502,018, both 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, 2014, Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015, and Part II, Item 1. "Legal Proceedings" of 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, 2014, Part II, Item 1. "Legal Proceedings" of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, and Part II, Item 1. "Legal Proceedings" of 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, for the treatment of rheumatoid arthritis and non-infectious uveitis; dupilumab, an antibody to IL-4R, for the treatment of atopic dermatitis, asthma, chronic sinusitis with 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 a lawsuit for patent infringement and assert their patents are valid and cover our late-stage antibody product candidates, similar to the patent infringement proceedings initiated by Amgen referred to above. As described in Part II, Item 1. "Legal Proceedings" of this report, we and Sanofi-Aventis U.S. LLC initiated invalidity actions against patents jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product and antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST nor EYLEA is a recombinant antibody. Genentech has licensed these patents to several different companies under confidential license agreements. If we desire a license for any of our antibody products or product candidates as part of a settlement for these invalidity actions and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to make recombinant antibodies in, or to import them into, the United States. 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.

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

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

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under "If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed," the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic and/or biosimilar versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the federal Patient Protection and Affordable Care Act, or PPACA, enacted in 2010, there is an abbreviated path in the United States for regulatory approval of biosimilar versions of biological products. 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. 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 a 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 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) EYLEA, Praluent, ZALTRAP, and ARCALYST, 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 corporate 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 corporate 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 permits from the local government, 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, in the future, our ability to manufacture our marketed products at additional facilities, 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 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. 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 corporate 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. 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 partnership with Eli Lilly), Johnson & Johnson, and AbbVie are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (Actemra®) for the treatment of rheumatoid arthritis, and several other companies, including Johnson & Johnson (in partnership with GlaxoSmithKline), Alder Biopharmaceuticals, Ablynx (in partnership with AbbVie), R-Pharm, and Pfizer have antibodies against IL-6 or IL-6R in clinical development. A number of companies are developing antibodies that, if approved, may compete with dupilumab, our IL-4R antibody, if it is approved, including Roche (an antibody against

IL-13), Teva (an antibody against IL-5), AstraZeneca (antibodies against IL-5R and IL-13), Novartis (a combination antibody against IL-4 and IL-13), and Amgen (in partnership with AstraZeneca) (an antibody against thymic stromal lymphopoietin, or TSLP). For muscle-wasting conditions, Pfizer, Eli Lilly, Bristol-Myers Squibb, and Atara Biotherapeutics have anti-GDF8 monoclonal antibodies in development, and Novartis has a competing antibody targeting ActRIIB. For RSV, competitors have antibodies in clinical development, including AstraZeneca (in partnership 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 the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (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. In March 2010, the PPACA and a related reconciliation bill were enacted in the United States. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by CMS and other federal and state agencies. Further, 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. 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.

Since EYLEA and Praluent for their currently approved indications will likely continue to be too expensive for most patients to afford without health insurance coverage, if third-party payers, including Medicare and Medicaid in the United States, do not continue to provide adequate coverage and reimbursement for EYLEA or do not provide adequate coverage and reimbursement for Praluent, our ability to successfully market them would be materially adversely impacted. 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

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profitability. In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

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

We sell EYLEA in the United States to several distributors and specialty pharmacies. Under this distribution model, the distributors and specialty pharmacies generally take physical delivery of product and generally sell the product directly to healthcare providers. For the nine months ended September 30, 2015 and 2014, we recorded 67% and 75%, respectively, of our total gross product revenue from sales to a single distributor, Besse Medical, a subsidiary of AmerisourceBergen Corporation. 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.

Regulatory and Litigation Risks

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

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

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

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

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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 has enacted provisions imposing reporting and disclosure requirements on pharmaceutical manufacturers for any "transfers of value" made to U.S. prescribers and certain other healthcare providers and teaching hospitals. These statutory provisions and related regulations (commonly known as the "Sunshine Act") require pharmaceutical manufacturers to report such transfers of value annually to the Secretary of the U.S. Department of Health and Human Services, which in turn aggregates and posts the information on a website managed by the Centers for Medicare & Medicaid Services. We will need to continue to dedicate significant resources to comply with these requirements. 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 and localities, including California, the District of Columbia, Massachusetts, Minnesota, Nevada, New Mexico, and Vermont, have enacted 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. Similar requirements are being considered in other states and already are in effect in a number of jurisdictions outside of the United States. 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.

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, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

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

prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

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

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

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

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

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

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

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

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

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

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- other laws and regulatory requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition");
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;

- our ability to deploy overseas funds in an efficient manner;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

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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, the availability of the U.S. research and development tax credit, and changes in tax laws and regulations.

We face potential liability related to the privacy of health information we obtain from research institutions and our collaborators.

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (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, is collaborating with the Geisinger Health System, which is subject to such regulations, and may enter into collaboration arrangements with additional institutions in the future. Regeneron is not a HIPAA-covered entity and our clinical research efforts are not directly regulated by HIPAA, so we are not subject to civil penalties under HIPAA. 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, international data protection laws, including the EU Data Protection Directive and legislation of the EU member states implementing it, may apply to some or all of the clinical data obtained from our collaborators outside of the U.S. Failure by those 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 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. 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.

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

If Sanofi does not elect to co-develop the product candidates that we discover or opts out of their development under our Antibody Collaboration or our IO Collaboration, unless we enter into a collaboration agreement with another party, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support those antibody products. For example, Sanofi has elected not to continue co-development of fasinumab, REGN2222, and REGN1033, and decided not to opt in to the REGN1193, 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. 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.

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

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

Risk Related to Employees

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

We are highly dependent on certain of our executive officers, other key members of our senior management team, and our Chairman. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; George D. Yancopoulos,

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

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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 have invested in 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 the first quarter of 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 HealthCare's sales of EYLEA outside the United States, or from other sources, the amount, timing, nature, or source of which cannot be predicted, we may incur substantial losses again as we conduct our research and development activities, commercialize our approved products, and prepare for possible commercialization of our other product candidates and new indications of our marketed products.

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

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. In addition, our expenses may increase for many reasons, including expenses in connection with the commercialization of EYLEA and Praluent and the anticipated commercial launches of our late-stage product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody product candidates we are developing on our own (without Sanofi), and expenses related to the requirement, following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates being

developed in collaboration with Sanofi.

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 are able to 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

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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, 2015, we had $654.6 million in cash and cash equivalents and $922.4 million in marketable securities (including $27.5 million in equity securities). Our investments consist primarily of fixed-income securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests. If any of our investments suffer market price declines that are other than temporary, their value could be impaired, which may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

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

- fluctuations in our operating results, in particular net product sales of EYLEA;
- if any of our product candidates or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and fluctuations in market share for, our marketed products, especially EYLEA and Praluent;
- whether our net products sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the European Patent Office and in the U.S. Patent and Trademark Office;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and pharmacy benefit management

companies) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;

- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;

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- 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 increasing its ownership of our Common Stock. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) is low relative to many large public companies. As our Common Stock is less liquid than the stock of companies with broader public ownership, its trading price may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2015, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 47.7% 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, 2015. As of September 30, 2015, Sanofi beneficially owned 23,016,992 shares of our Common Stock, representing approximately 22.5% 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 July 2014, Sanofi disclosed in an amendment to its Schedule 13D filed with the SEC its intention to purchase additional shares of our Common Stock to progressively increase its beneficial ownership in 2014 and 2015 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.

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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, 2015, holders of Class A Stock held 15.8% 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, 2015:

- our current executive officers and directors beneficially owned 10.0% 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, 2015, 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, 2015; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 47.7% 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, 2015. In addition, these five shareholders plus our Chief Executive Officer held approximately 53.5% 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, 2015.

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

In addition, upon Sanofi reaching 20% ownership of our then outstanding shares of Class A Stock and Common Stock (taken together), we are required under the amended and restated investor agreement to appoint an individual agreed upon by us and Sanofi to our board of directors. Subject to certain exceptions, we are required to use our reasonable efforts (including recommending that our shareholders vote in favor) to cause the election of this designee at our annual shareholder meetings for so long as Sanofi maintains an equity interest in us that is the lower of (i) the highest percentage ownership Sanofi attains following its acquisition of 20% of our then outstanding shares of Class A Stock and Common Stock (taken together) and (ii) 25% of our then outstanding shares of Class A Stock and Common Stock (taken together). This designee is required to be "independent" of our company, as determined under NASDAQ rules, and not to be a current or former officer, director, employee, or paid consultant of Sanofi. In April 2014, Sanofi notified us that it had reached the 20% ownership threshold and designated Robert A. Ingram as its designee. On April 4, 2014, following recommendation of the Corporate Governance and Compliance Committee, the board of directors elected Mr. Ingram as a director and a member of the Compensation Committee. Mr. Ingram was subsequently elected as a Class I director at our 2014 Annual Shareholder Meeting for a term expiring at the 2016 Annual Shareholder Meeting.

The convertible note hedges and 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 our offering of our 1.875% convertible senior notes due October 1, 2016, we entered into convertible note hedge transactions with four financial institutions (the hedge counterparties), the purpose of which was to reduce the potential dilution to our Common Stock and/or offset potential cash payments in excess of the principal amount of the notes (as applicable) upon conversion of the notes. In the event that the hedge counterparties fail to deliver shares to us or potential cash payments (as applicable) as required under the convertible note hedge

documents, we would not receive the benefit of such transactions. Separately, we also entered into warrant transactions with the hedge counterparties. The warrant transactions could separately have a dilutive effect from the issuance of Common Stock pursuant to the warrants. As of September 30, 2015, an aggregate principal amount of $33.1 million of the notes and 2,225,068 warrants (subject to adjustment from time to time as provided in the applicable warrant agreements) remained outstanding.

In connection with hedging these transactions, the hedge 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 prior to maturity of the notes (and are likely to do so during any conversion period related to any conversion of the notes). 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 and could have

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the effect of increasing or preventing a decline in the value of our Common Stock during any cash settlement averaging period related to a conversion of the notes.

In addition, we intend to continue to exercise options under the convertible note hedge transactions whenever notes are converted. In order to unwind their hedge position with respect to the options we exercise, the hedge counterparties and/or their affiliates may sell shares of our Common Stock or other securities in secondary market transactions or unwind various derivative transactions with respect to our Common Stock during the cash settlement averaging period for the converted notes. The effect, if any, of any of these transactions and activities on the trading price of our Common Stock or the notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our Common Stock and the value of the notes. The derivative transactions that the hedge counterparties and/or their affiliates expect to enter into to hedge these transactions may include cash-settled equity swaps referenced to our Common Stock. In certain circumstances, the hedge counterparties and/or their affiliates may have derivative positions that, when combined with the hedge counterparties' and their affiliates' ownership of our Common Stock, if any, would give them economic exposure to the return on a significant number of shares 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 our convertible senior notes and related warrant and hedge transactions, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

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

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

Pursuant to the January 2014 amended and restated investor agreement between us and Sanofi, Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of our company or acquiring more than 30% of our Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of our License and Collaboration Agreement with Sanofi relating to our Antibody Collaboration or our ZALTRAP collaboration agreement with Sanofi, each as amended; (ii) our announcement recommending acceptance by our shareholders of a tender offer or exchange offer that, if consummated, would constitute a change of control involving us; (iii) the public announcement of any definitive agreement providing for a change of control involving

us; (iv) the date of any issuance of shares of Common Stock by us that would result in another party having more than 10% of the voting power of our then outstanding Class A Stock and Common Stock (taken together) unless such party enters into a standstill agreement containing certain terms substantially similar to the standstill obligations of Sanofi; or (v) other specified events, such as a liquidation or dissolution of our company.

Similarly, under our 2014 PDGFR-beta license and collaboration agreement with Bayer HealthCare, Bayer HealthCare 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). 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

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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 HealthCare; or (v) other specified events, such as a liquidation or dissolution of our company.

The holders of our convertible senior notes have fundamental change purchase rights, which require us to purchase all or a portion of their notes upon the occurrence of a fundamental change, as defined in the indenture governing the notes. In addition, the indenture contains provisions requiring an increase to the conversion rate for conversions in connection with make-whole fundamental changes. These rights and provisions may in certain circumstances delay or prevent a takeover of us and the removal of incumbent management that might otherwise be beneficial to investors. In addition, upon the occurrence of certain extraordinary events, the hedge transactions would be exercised upon the conversion of notes, and the warrant transactions may be terminated. It is possible that the proceeds we receive upon the exercise of the convertible note hedge transactions would be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. Such differences may result in the acquisition of us being on terms less favorable to our shareholders than it would otherwise be.

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 has served on our board of directors since April 2014. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

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

In the third quarter of 2015, we settled the conversion of $2.0 million principal amount of our 1.875% convertible senior notes through the payment of $2.0 million in cash (equal to the principal amount of the converted notes) and issuance of 20,218 shares of our Common Stock to the holders of the notes surrendered for conversion. We issued and sold the notes in October 2011 in a private placement in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. In connection with this conversion, we exercised a proportionate amount of our convertible note hedges, as a result of which we received from our hedge counterparties 20,212 shares of our Common Stock.

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 2015.

| 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 |
|---|---|---|---|---|
| 9/1/2015-9/30/2015 | 3,277 | $538.42 | — | — |

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ITEM 6. EXHIBITS

(a) Exhibits

| Exhibit Number | | Description |
|---|---|---|
| 10.1 | * | Immuno-oncology Discovery and Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between Regeneron Pharmaceuticals, Inc. (the "Registrant") and Sanofi Biotechnology SAS. |
| 10.2 | * | Immuno-oncology License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS. |
| 10.3 | * | Amendment No. 1 to Amended and Restated Discovery and Preclinical Development Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. |
| 10.4 | * | Amendment No. 2 to Amended and Restated License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. |
| 10.5 | | Second Amendment, dated as of August 5, 2015, to the Master Terms and Conditions for Warrants, between Morgan Stanley & Co. International plc and the Registrant. |
| 10.6 | | Seventeenth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of August 10, 2015. |
| 10.7 | * | Collaboration Agreement, dated as of September 29, 2015, by and between Regeneron Ireland and Mitsubishi Tanabe Pharma Corporation. |
| 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 |

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* 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, 2015

By: /s/ Robert E. Landry

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